Intracardiac echocardiography for guidance of transcatheter aortic valve implantation under monitored sedation: a solution to a dilemma?

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Transcatheter aortic valve implantation (TAVI) has been established as a valuable alternative to surgical aortic valve replacement in patients deemed to have high or prohibitive perioperative risk. However, there are several technical constraints and procedural risks inherent to TAVI. These risks include annulus rupture, ventricular perforation, aortic dissection, coronary occlusion, and dislodgement or migration of the valve prosthesis to the aorta or the left ventricle (LV). Other complications may be related to inappropriate valve deployment and subsequent paravalvular leak. Most complications cannot be detected at an early stage without echocardiographic guidance. Although not addressed by current guidelines, some European centres have advocated a ‘minimalist’ approach with exclusively fluoroscopic and angiographic guidance. Transoesophageal echocardiography (TEE), including real-time three-dimensional (RT-3D) imaging, has been established as a standard approach for peri-interventional guidance of TAVI. However, TEE monitoring almost always necessitates general anaesthesia and endotracheal intubation. A potential alternative to TEE is intracardiac echocardiography (ICE) that may provide a solution to a common dilemma: the most important advantage of ICE being the compatibility with monitored anaesthesia care without endotracheal intubation. Other advantages of ICE include uninterrupted monitoring, no fluoroscopic interference, and precise Doppler-based assessment of pulmonary artery pressures. Limitations of ICE include the need for additional venous access, the learning curve associated with a new device, and potentially increased cost.

Keywords

- transcatheter aortic valve replacement
- peri-procedural guidance
- intracardiac echocardiography
- transoesophageal echocardiography
- three-dimensional imaging

Introduction

Transfemoral (TF) transcatheter aortic valve implantation (TAVI) has been established as a catheter-based alternative to open heart surgery in high-risk patients with symptomatic aortic stenosis (AS) and sufficient femoral and pelvic vasculature. TAVI also represents the only therapeutic approach that can improve prognosis in inoperable patients.1–3 Current generation TAVI devices allow for a dedicated percutaneous approach with improvements in device delivery making general anaesthesia and endotracheal intubation an unnecessary complication of the procedure. Given the advancements in TAVI devices, European and American centres have advocated for angiographic- and fluoroscopic-based ‘minimalist’ TAVI approach without echocardiographic guidance or with intermittent transthoracic echocardiographic (TTE) assessment.4–6 However, current guidelines do not address angiographic-/fluoroscopic-only guidance but rather continue to advocate for transoesophageal echocardiography (TEE) support, including three-dimensional (3D) imaging for TAVI.7–9 TEE has several advantages over angiographic or fluoroscopic guidance: (i) significant reduction in the use of radio contrast;10 (ii) effective imaging to support crossing the native aortic valve; (iii) help with adequate balloon positioning for pre-dilation and deployment of the transcatheter heart valve (THV);11–13 and (iv) detection of life-threatening complications at an early stage.14–16 Potential adverse complications that can be detected by TEE include annulus rupture,17,18 perforation of the myocardium with subsequent pericardial haemorrhage,19 coronary ostia occlusion with subsequent myocardial ischaemia,20 aortic perforation or dissection,19 THV malpositioning or dislodgement,21 and paravalvular leak.22 Although two-dimensional (2D) and RT-3D TEE is considered the echocardiographic method of choice for pre-procedural assessment,12,13,23,24 this approach is not ideal for intra-procedural guidance of TF TAVI. And TTE cannot be considered an adequate surrogate given its inability to provide continuous and...
detailed procedural guidance. A potential solution to the TAVI procedural simplification dilemma is the introduction of intracardiac echocardiography (ICE) (Figure 1).

Why is a new echocardiographic guiding tool desirable?

The need for a new echocardiographic imaging modality is a product of several factors: the limitations of both TTE and TEE to serve as guiding tools during TAVI (Table 1); new options and requirements to simplify the TAVI procedure; and the persisting rationale and importance of continuous echocardiographic monitoring and guidance. Consequently, there is a need to improve and simplify the TAVI procedure without increasing procedural risk.

Limitations of TEE guidance during TAVI

Although both feasible and beneficial, the use of TEE guidance during TAVI is based on initial experience; however, there has been diminishing use of TEE for TF TAVI procedures. General anaesthesia and endotracheal intubation for TAVI has increasingly been omitted in TF TAVI procedures over the last few years. Only a few centres consider TEE acceptable in patients undergoing conscious sedation for TAVI. Other limitations and reasons for decreased use of TEE guidance include: interference with fluoroscopic viewing; lack of coaxiality of the Doppler beam with the ascending aorta and transaortic flow; and the additional support staff required for TEE guidance. TEE provides intermittent rather than continuous monitoring as the TEE probe impedes fluoroscopic viewing and needs to be withdrawn and repositioned several times during a TAVI procedure. This is of particular importance when it comes to THV deployment. The operator usually prefers to have an unimpeded fluoroscopic view of the delivery system, which is often obstructed by the position of the TEE probe. TEE is therefore barely adequate to take full advantage of echocardiography to position the THV or to detect complications as early as possible. When considering acute kidney injury (AKI), which is a strong and independent predictor of 30-day and 1-year mortality after TAVI, there is a need for a contrast-independent, continuous imaging modality (Table 1).

It is unclear whether omitting TEE as an imaging tool during TAVI has an effect on outcomes. The lack of imaging may be compensated by operator experience, improved valve technology and deliverability, shorter procedural times, and monitored rather than general anaesthesia. However, the importance of imaging guidance likely

Figure 1 Procedural setting for ICE in TAVI.
depends on individual patient peri-procedural risk with patients with higher risk and complex anatomy benefiting the most from imaging.

Implications of purely percutaneous TAVI

Most centres do not perform a surgical cut-down to expose the femoral artery in TF TAVI as the current iteration of TAVI devices requires access sheath sizes of only 16F or less. Consequently, general anaesthesia with endotracheal intubation has become dispensable and replaced by local anaesthesia and monitored anaesthesia care (MAC). TEE is generally not accepted as compatible with MAC over long periods and has therefore increasingly become obstructive in the development of a simplified TAVI procedure. Technical easing, mainly characterized by a completely percutaneous and angiography/fluoroscopy-guided approach, has been gaining ground. Some centres have TTE available during TAVI as a surrogate for TEE. However, TTE has several limitations that need to be considered: TTE interrupts the TAVI workflow to acquire images; patients are supine during the procedure making imaging difficult; and only intermittent TAVI guidance can be provided. TTE can only be used for a limited assessment of ventricular function, evaluation of interventional result, or to rule out pericardial hemorrhage. The current discussion in terms of the best strategy for performing TAVI as safe and as smoothly as possible is not clear and leads to the question: TEE or TTE, or just fluoroscopy and angiography? The answer is none of these are really adequate.

Intracardiac echocardiography

Echocardiography has a critical peri-procedural role in catheter-based structural heart disease interventional procedures. ICE has been established as a valuable intra-procedural guiding tool in device closure of interatrial communications and in electrophysiological interventions. ICE was initially introduced as a guiding tool with first-generation TAVI devices but has evolved over the last few years. There is growing interest in the use of ICE with the transition to a purely dynamic gradient changes can be critical during the procedure. In particular, procedures such as device closure of interatrial communications have become independent of general anaesthesia. ICE guidance for these procedures has also led to shortening of fluoroscopy and procedural time.

What are the requirements for an ideal guiding tool for TAVI?

An ideal image tool for guiding TAVI should have the following requirements: (i) the imaging modality should be portable and compatible with MAC; (ii) should be capable of displaying any step of the procedure by uninterrupted monitoring to help with maneuvering of catheters and devices; (iii) able to adequately detect any untoward event at the earliest possible stage; and (iv) has to be safe for the patient. An ideal tool should not interfere with fluoroscopic or angiographic imaging or with the devices needed for the TAVI procedure itself. Moreover, the image resolution should be high enough to identify the smallest structures and pathological changes, e.g. chordae tendineae or thrombotic appositions. Given the increased mortality associated with AKI, an ideal imaging modality would avoid or decrease the use of contrast exposure. An important quality and safety requirement is the need to provide Doppler-derived haemodynamic data, such as pressure gradients and estimated pulmonary artery pressure (PAP), since many TAVI patients present with severe pulmonary hypertension where dynamic gradient changes can be critical during the procedure. The imaging modality should also have the ability to assess the final TAVI result and the severity of paravalvular leak. RT-3D capability, including 3D color mapping, is desirable as well. Finally, easy learnability and feasibility matter just as much as avoidance of an increase in total cost.

Standard approach for ICE guidance in TAVI

ICE is readily available 9 Suboptimal image quality with pts. in supine position

Table 1

<table>
<thead>
<tr>
<th>Modality</th>
<th>Advantages</th>
<th>Disadvantages and limitations</th>
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<tbody>
<tr>
<td>TTE</td>
<td>Readily available</td>
<td>Suboptimal image quality with pts. in supine position</td>
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<tr>
<td></td>
<td>Low cost</td>
<td>Interference with fluoroscopy</td>
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<td></td>
<td>Non-invasive</td>
<td>No continuous guidance, interrupts procedure</td>
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<td></td>
<td>No additional sedation</td>
<td>Technologist/echocardiograph required</td>
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<tr>
<td>TEE</td>
<td>Excellent image quality</td>
<td>Additional sedation/anaesthesia required</td>
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<tr>
<td></td>
<td>3D imaging adds to 2D</td>
<td>Endotracheal intubation required in many cases</td>
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<tr>
<td></td>
<td>Low-contrast consumption</td>
<td>Echocardiographic operator required</td>
</tr>
<tr>
<td></td>
<td>Low cost</td>
<td>Semi-invasive</td>
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<tr>
<td>ICE</td>
<td>No additional sedation</td>
<td>High cost</td>
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<tr>
<td></td>
<td>Excellent image quality</td>
<td>Learning curve; training required</td>
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<tr>
<td></td>
<td>Lower contrast consumption</td>
<td>Invasive</td>
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<td></td>
<td>Interventionalist autonomy</td>
<td>Low impact of 3D with current systems</td>
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3D, three-dimensional; 2D, two-dimensional; ICE, intracardiac echocardiography; pts., patients; TAVI, transcatheter valve implantation; TEE, transthoracic echocardiography; TTE, transthoracic echocardiography.
percutaneous TF TAVI approach performed under MAC sedation. ICE is performed either with an 8-F AcuNav™-catheter for 2D or with a 10-F AcuNav™-catheter for RT-3D imaging (Siemens Inc., Erlangen, Germany) linked by SwiftLink™ Adapters to either an SC2000 Ultrasound Unit (Acuson-Siemens Inc., Mountain View, CA, USA) or a compact size Vivid Q Ultrasound Laptop (GE Healthcare, Little Chalfont, Buckinghamshire, UK). For TAVI monitoring, the steerable ICE catheter is introduced into the femoral vein and advanced through the inferior vena cava and the right atrium (RA) to the superior cavo-atrial junction. Utilization of a 45-cm-long 9 F or 10 F access sheath is recommended to avoid navigation of the wireless catheter through the venous pelvic vasculature. While in the RA, co-existent tricuspid regurgitation can be interrogated from the ‘Home View’ position by continuous wave (CW) Doppler to estimate systolic and mean PAP (Figure 2). In addition to the ‘Home View’, three other standard cut planes have been defined for adequate monitoring and guidance during TAVI: longitudinal, short-axis, and transventricular views.

The longitudinal view from the cavo-atrial junction (Figure 3) is obtained with the tip of the catheter slightly tilted towards the adjacent ascending aorta and is considered the main ICE view to be maintained throughout the procedure. This view provides a continuous display of the entire aortic morphology, including sino-tubular junction, aortic bulb, and native aortic valve. The left ventricular outflow tract is usually multiplexed by reverberations owing to the calcified valve. Placement of any hardware including wires, catheters, and the THV mounted on a delivery balloon catheter can be precisely monitored. After aligning the Doppler beam with transvalvular flow, the ICE catheter’s steering mechanism can be locked to maintain this setting.

After THV deployment, the short-axis view is obtained with the catheter in the RA and the tip tilted by 90° towards the aortic annulus to rule out annulus dissection and to check for transvalvular and paravalvular leak (Figure 4). The severity of any paravalvular regurgitation can be evaluated with a multi-parametric approach mainly based on color Doppler. RT-3D ICE color mapping may facilitate quantification of leaks. According to TEE-based evaluation of paravalvular leaks, a semi-quantitative measurement is the ratio between total circumferential extent of periprosthetic regurgitant flow and circumference of the left ventricular outflow tract.

From a position with the tip tilted towards the tricuspid valve, the ICE catheter can be easily advanced into the right ventricle to obtain the transventricular long-axis view of the left ventricle, which is similar to a parasternal long-axis TTE view displaying the mitral valve, the valvular apparatus, left ventricular cavity, and left ventricular outflow tract (Figure 5). This view is helpful to confirm adequate wire position prior to pre-dilatation but is mostly used to check for impairment of left ventricular function and to detect possible pericardial haemorrhage after THV deployment.

**RT-3D ICE**

A 22 × 90° volume image is provided by a miniaturized probe. Clinical or experimental data are pending leaving users ambivalent about the clinical value of RT-3D ICE. The small image volume represents the main limitation of RT-3D ICE, with the rendered volume falling...
short of expectations and having a less significant impact on the guidance of TAVI compared with RT-3D TEE (Figure 6). RT-3D color Doppler ICE displays flow after valve deployment and may facilitate detection of leaks or other malfunction. In addition, the operator can take advantage of simultaneously viewing the flow in two perpendicular cut plains (Figure 7).

**How to derive benefit from ICE in TAVI?**

ICE guidance and monitoring have been demonstrated to be effective, safe, and, after a short learning curve, user friendly. However, ICE represents a niche method that imaging cardiologists or even experts in echocardiography are rarely familiar. Most interventional cardiologists are also not acquainted with this technique. The best way for TAVI operators to derive benefit from ICE is to train and assist an imaging cardiologist who should be experienced in TEE to maneuver the ICE catheter and interpret the images. An ideal position for the imaging cardiologist is across from the main operator where venous access for the ICE catheter is opposite the main femoral arterial access for TAVI (Figure 1).

A multimodality imaging strategy integrating fluoroscopy and ICE for TAVI guidance does not prolong the implantation procedure but rather minimizes utilization of angiography. The average amount of contrast medium needed for the whole procedure could be reduced to 20.1 ± 8.7 mL, decreasing the probability and severity of AKI after TAVI, and potentially shortening the in-hospital stay by 3.7 days on average. Progression of pre-existing or new

**Figure 4** Short-axis view with the catheter tip tilted in the right atrium by 90° towards the aortic annulus, (A) graphic (modified from Bartel et al.) showing the appropriate catheter position, (B) mild paravalvular leak comprising <10% of the circumference, (C) severe paravalvular leak comprising >20% of the circumference, and (D) no paravalvular leak after post-dilatation. ICE, intracardiac echocardiography; PL, paravalvular leak; RV, right ventricle; SVC, superior vena cava; THV, transcatheter heart valve.

**Figure 5** Transventricular view with the catheter in the right ventricle and the probe aimed to the left ventricle, (A) graphic showing the appropriate catheter position and (B) hypertrophied left ventricle. LA, left atrium; LV, left ventricle; RA, right atrium; RV, right ventricle.

**Figure 6** Procedural guidance using three-dimensional intracardiac echocardiography, (A) pre-dilatation of the stenotic valve, (B) retrograde advancement of a transcatheter heart valve mounted on a balloon catheter, (C) the transcatheter heart valve is now at an adequate level for implantation, and (D) valve deployment with the valve balloon fully inflated. 1, long excess sheath in the right atrium housing the pacemaker lead; B, balloon inflated for pre-dilatation; PT, pigtail catheter placed in the non-coronary cusp; THV, transcatheter heart valve.
The development of renal dysfunction can be avoided, potentially improving the outcome after TAVI. The procedure can also be completed with less fluoroscopy time than conventional TAVI. ICE-based Doppler measurements were also shown to provide reliable haemodynamic data, complementing echocardiographic guidance. In particular, pulmonary hypertension was demonstrated to improve in 37% of patients immediately after TAVI. ICE guidance may even replace right heart catheterization for PAP monitoring, which is usually indicated in primarily high-risk TAVI candidates presenting with pulmonary hypertension and chronic kidney disease (Table 2). This approach combines the advantages of MAC with uninterrupted echocardiographic and haemodynamic guidance.

Continuous ICE monitoring can also detect bleeding complications prior to deterioration of the patient (Figure 8). Very high-risk patients who usually do not tolerate any haemodynamic derangement may benefit the most from early detection and response to a complication. ICE also provides semi-quantitative measures of paravalvular leak to help guide post-dilatation for optimizing the final result (Figure 4).

Limitations

The most important limitation of the ICE catheter is the cost of each device. However, the cost of using ICE needs to be considered in the context of the potential savings provided by shorter procedural times and optimal results and from avoiding general anaesthesia and complications. These advantages can translate into shorter hospital stays and overall reduction in cost that needs to be weighed against the price of one ICE catheter. The cost-saving potential is not the same for every patient or for each ICE application and depends on the individual risk with higher risk patients deriving the most benefit. One also needs to consider the cost of ICE in relation to the overall costs of the interventional procedure.

In the USA, average global hospital and physician charges are similar when using ICE or TEE for intra-procedural guidance (USD 34,861 + 43,759 vs. USD 32,812 + 2,656, respectively, \( P = 0.107 \)). In Europe, health insurance agencies usually do not cover the costs of ICE catheters limiting the adoption of ICE in the region. However, in many European countries, a conventional intravascular ultrasound examination can be billed separately. Re-sterilization and re-use of ICE catheters, permitted only in Germany and in Eastern Europe, lower the costs. However, re-sterilization should be handled with caution and performed by companies specialized in the sterilization of such products and who can guarantee the safety of reusing ICE catheters. Shorter turn-around times resulting from the use of MAC vs. general anaesthesia with endotracheal intubation may add to the relative value of ICE imaging.

Another potential limitation of ICE in TAVI is possible interference with the pacemaker lead needed for rapid pacing and the risk of dislodgement. Physicians who are not as experienced with ICE need to pay particular attention to pacemaker dislodgement as this could lead to lack of capture and consequent migration of the THV during valve deployment. Therefore, pacemaker threshold and position should be rechecked after navigating the ICE catheter into the right ventricle. Adjustment of the transventricular long-axis view may be avoided in patients who become pacemaker dependent after THV implantation.
Additional disadvantages of ICE guidance in TAVI also include the need for insertion of a second venous sheath; the danger of potentially provoking transient atrial and ventricular arrhythmias; a limited field of view if RT-3D ICE is used; and the need for supplemental training of invasive and non-invasive cardiologists (Table 1). Additional costs derived from RT-3D in comparison to 2D ICE are currently not justified, although experience with this technology from single centres is promising.38

Conclusions

MAC sedation as a dedicated replacement for general anaesthesia with endotracheal intubation is barely compatible with TEE during TFTAVI but decreases the complexity and potentially the risk of the procedure. However, continuous imaging guidance during THV implantation is particularly important in patients deemed to be on very high risk for peri-procedural complication. This competing dilemma cannot be resolved by omitting the use of echocardiography or by using intermittent TTE. Continuous echocardiographic monitoring by ICE provides favourable imaging quality, potentially reduces the risk of complication with TAVI, and is safe to perform. TAVI performed under ICE guidance requires lower doses of contrast and is associated with a lower risk of AKI. ICE can be recommended as an alternative guiding tool for TF TAVI, especially in high-risk patients.

Conflict of interest: none declared.

References

A 70-year-old female with symptomatic severe functional mitral valve regurgitation (Panel A) underwent successful mitral valve repair utilizing a Carbomedics 34-mm flexible annuloplasty ring with trivial residual regurgitation postoperative (Panel B). Pre-discharge transthoracic echocardiogram showed a mean gradient of 3 mmHg at 60 bpm (Panel C).

The patient presented with recurrent exertional dyspnoea 7 months later. Transthoracic echocardiography showed trivial mitral regurgitation, but a high resting mitral inflow gradient of 10 mmHg at 70 bpm (Panel D) which increased during supine bicycle stress echocardiography to 25 mmHg (Panel E) at peak heart rate of 126 bpm with concomitant rise in pulmonary artery systolic pressure from 43 mmHg at rest to 75 mmHg at peak exercise, explaining the recurrent symptoms. She was referred for redo mitral valve surgery after failing medical management.

Intraoperative transoesophageal echocardiography showed extensive tissue ingrowth encroaching into supravalvular mitral inflow orifice, extending far over the annuloplasty ring (Panel F, arrow), causing significant stenosis of the mitral valve orifice (Panel G, arrows). During surgery, extensive tissue ingrowth was noted over the top of the mitral annuloplasty ring, consistent with a large ledge of pannus (Panel H, arrow). The mitral valve was replaced with a Hancock II 27-mm porcine bioprosthesis (Panel I; Supplementary data online, Video S1). Pathology confirmed fibrous tissue with chronic inflammation consistent with pannus.

Pannus formation after annuloplasty ring mitral valve repair is extremely rare and typically diagnosed many years after surgery. Rapid pannus ingrowth should be considered in the differential diagnosis when a patient presents with a progressive increase of the mitral inflow gradient early after successful mitral valve repair.

Supplementary data are available at European Heart Journal – Cardiovascular Imaging online.