Transthoracic echocardiography is adequate for intraprocedural guidance of transcatheter aortic valve implantation

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Abstract

Background: While transcatheter aortic valve implantation (TAVI) has traditionally been supported intraprocedurally by transoesophageal echocardiography (TOE), transthoracic echocardiography (TTE) is increasingly being used. We evaluated echocardiographic imaging characteristics and clinical outcomes in patients who underwent TTE during TAVI (TTE-TAVI).

Methods and results: A select team of dedicated sonographers and interventional echocardiographers performed TTE-TAVI in 278 patients, all of whom underwent TAVI through transfemoral access. We implanted the Medtronic EVOLUT R valve in 258 patients (92.8%). TTE images were acquired immediately pre-procedure by a dedicated sonographer in the cardiac catheterization laboratory with the patient in the supine position. TTE was then performed post deployment of TAVI. In the procedure, TTE image quality was fair or better in 249 (89.6%) cases. Color-flow Doppler was adequate or better in 275 (98.9%) cases. In 2 cases, paravalvular regurgitation (PVL) could not be assessed confidently by echocardiography due to poor image quality; in those cases, PVL was assessed by fluoroscopy, aortic root injection and invasive hemodynamics. Both TTE and invasive hemodynamics were used in the assessment of need for post-deployment stent ballooning (n=23, 8.3%). TTE adequately recognized new pericardial effusion in 3 cases. No case required TOE conversion for image quality. There was only 1 case of intraprocedural TTE failing to recognize moderate PVL, without clinical implication. In 99% of patients, TTE-TAVI adequately assessed PVL compared with 24-h and 1-month follow-up TTE.

Conclusions: With the current generation of TAVI, TTE-TAVI is adequate intraprocedurally when performed by specialized sonographers and dedicated cardiologists in a highly experienced TAVI center.
Introduction

Transcatheter aortic valve implantation (TAVI) traditionally has been supported by intraprocedural transoesophageal echocardiography (TOE). TOE has considerable uses during the TAVI procedure, including observation of and assistance with position of catheters, valve sizing, evaluation of stent position and monitoring for complications of the procedure (1). Perhaps the most crucial role of TOE is in the assessment of paravalvular aortic regurgitation (PVL), which is one of the most significant indicators of clinical outcome post TAVI (2). TAVI technology has gradually matured since the first clinical trials (3, 4), and sheath sizes, complication rates and significant PVL have all decreased in the current era, particularly in experienced centers (5). Given maturing technology and fewer complications, TAVI centers also have shifted away from general anesthesia as experienced centers have become more facile with TAVI under monitored anesthesia care (MAC) or conscious sedation in an effort to reduce both patient morbidity and cost (6). TAVI guided by transthoracic echocardiography (TTE) thus has become advantageous because it does not require intubation of the esophagus, eliminating associated morbidity and potential complications. We describe our experience with TTE for intraprocedural monitoring (TTE-TAVI) with current generation TAVI, highlighting imaging characteristics and clinical outcomes. To the best of our knowledge, this is the first study systematically evaluating the effectiveness of transthoracic imaging in TAVI procedures.

Methods

Aurora Health Care is an integrated health care system in eastern Wisconsin and northern Illinois. The Multidisciplinary Valve Program consists of a Heart Valve Team of dedicated interventional cardiologists, cardiac surgeons, interventional echocardiographers, anesthesiologists and clinical and research coordinators. The Heart Valve Team reviews all patients who are candidates for transcatheter valve interventions, and to date, 1200 TAVI procedures have been performed at Aurora St. Luke’s Medical Center, Milwaukee, Wisconsin.

TAVI procedures are performed in our hybrid operating and cardiac catheterization laboratory room. Prior to July 2015, all patients received general anesthesia and endotracheal intubation with TOE for intraprocedural guidance. A TOE transducer was then inserted into the esophagus, and an interventional echocardiographer would proceed with pre-procedural imaging to evaluate the aortic valve and cardiac structures. The TOE transducer would remain in place throughout the procedure to guide catheters if required and to evaluate for potential complications during TAVI. After TAVI deployment, TOE was used to evaluate stent depth, stent frame shape and valve leaflets, as well as the presence and severity of PVL and other potential complications.

As part of an effort to reduce hospital length of stay and improve procedural morbidity in our patients, the Heart Valve Team considered MAC sedation for TAVI in lieu of general anesthesia. We discussed the risks of TOE use in patients in the supine position who did not have an endotracheal tube and sought to explore the use of TTE instead of TOE during TAVI. We initially piloted TTE-TAVI in a select group of 20 patients who presented for TAVI from July to October 2015. All had a permanent pacemaker, and in each case, an iliofemoral approach and MAC sedation were utilized. Given our initial success with this approach, we made TTE-TAVI and MAC sedation the de facto approach for all TAVI procedures, with TOE as a bail-out strategy should TTE images be suboptimal or complications arise that would benefit from TOE investigation. Exceptions were made only in cases in which the anesthesiologist recommended against MAC sedation or when the procedural approach was planned as a direct aortic or transapical route. This report summarizes our initial efforts with a MAC and TTE-TAVI de facto strategy during the time period of November 2015 to December 2016.

TTE-TAVI was performed in the hybrid cardiac catheterization-operating room at Aurora St. Luke’s Medical Center. Valve sizing was performed with gated cardiac computed tomography (CT). After each patient received MAC sedation and the central catheter and transvenous pacemaker (if required) were placed, TTE images were obtained in the supine position by a cardiac sonographer under direct guidance of an assigned interventional echocardiographer; parasternal and apical views were obtained with and without color Doppler to assess aortic valve calcification, the left ventricular outflow tract, left ventricular ejection fraction and the presence of pericardial effusion. TTE was periodically used at other points during the procedure to assist with placement or positioning of catheters. The TAVI stent was positioned using fluoroscopy. Immediately after TAVI deployment, TTE images were again performed: stent depth, shape and
expansion were assessed in the parasternal long-axis view and short-axis view. Leaflet motion also was evaluated. Transvalvular aortic regurgitation and PVL were assessed using color Doppler in both parasternal long-axis and short-axis views and apical 3-chamber and 5-chamber views. We also evaluated the presence and severity of complications of TAVI. Assessment of PVL was made using established guidelines from the Valve Academic Research Consortium-2 (VARC-2) definitions (7). We utilized TTE to evaluate PVL again at 24 h post TAVI and at 1-month follow-up.

As all echocardiography laboratories store echocardiograms on a single common platform (stored in Synapse Cardiovascular, Fujifilm; Stamford, CT, USA), we were able to query all patients who underwent TTE for intraprocedural guidance of TAVI, examining their pre-TAVI TTE, TTE-TAVI, 24-h post-TAVI TTE and 30-day follow-up TTE. Clinical variables were queried from our ongoing valve registry and from the electronic clinical record (EPIC Systems, Verona, WI, USA). Pre-procedure TTE and 30-day follow-up TTE were performed by a variety of sonographers on multiple echocardiography machines (GE VIVID E95, GE VIVID E9; Waukesha, WI, USA; Philips IE33, Philips EPIQ). The intraprocedure TTE and 24-h post TTE were performed only at Aurora St. Luke’s Medical Center, using GE VIVID E95 and GE VIVID E9 platforms. These echocardiograms were performed by a small, core group of cardiac sonographers and interpreted by a core group of interventional echocardiographers who form the interventional echocardiography program. These echocardiograms were re-reviewed by a sonographer and cardiologist (D I, R J) to evaluate the overall image quality of the echocardiogram (excellent, good, fair, poor) using the same definitions we use in our echocardiography laboratory and document on all TTE reports. Excellent image quality = ideal image clarity of all cardiac components (myocardium, endocardium, chambers, valve leaflets and valve motion, color and spectral Doppler) with no artifacts. Good image quality = all cardiac components are visualized, but not ideally – no image-limiting artifacts are visualized. Fair image quality = some components are not adequately visualized and/or image-limiting artifacts are visualized. Poor = the majority of the components are not adequately visualized and/or significant image-limiting artifacts are seen. We then reviewed the ability to achieve adequate parasternal and apical views, using a 3-point scale (optimal quality, adequate quality and suboptimal quality). We assessed the quality of color Doppler to assess PVL using the same 3-point scale. We also evaluated the ability to visualize TAVI depth, stent frame shape and leaflets using the 3-point scale.

All clinical data were collected and analyzed using STATA, version 12.0 (STATA, College Station, TX, USA). Categorical variables were summarized as frequency and percentage, and continuous variables were summarized using means and standard deviations. The chi-squared test was used to compare categorical variables. Pre- and post-TAVI comparisons were conducted using McNemar’s test. Odds ratios were calculated when appropriate. Statistical significance was defined as a two-sided P value ≤0.05.

Ethical consideration

The study was approved by the Aurora Institutional Review Board, which serves as a governing body in determination of the ethics and scientific merit of clinical research at our institution. All research was conducted according to the ethical principles of the International Declaration of Helsinki for research conducted using human subjects. All patients participated and signed written informed consent for the TAVI procedure (including anesthesia and echocardiography). In view of the retrospective nature of this study, the Aurora Institutional Review Board waived informed consent for patients to be included in this study.

Results

TTE-TAVI was performed in 278 patients during the 14-month period. During that time period, an additional 19 patients had TAVI performed under general anesthesia with TOE. In 14 of the 19 cases, general anesthesia was employed because these patients required a direct aortic access approach for TAVI. In the remaining 5 of 19 cases, our cardiac anesthesiologists determined that these patients were not candidates for MAC sedation due to severe sleep apnea (n=2) or class IV heart failure (n=3). There were no significant clinical differences between these 19 patients and the TTE-TAVI cohort. Two of the 19 patients died prior to discharge, one as a result of acute respiratory failure 48 h post TAVI and the other as a result of multi-organ failure from vasodilatory shock. There were no complications of TOE or general anesthesia in these patients, and these 19 patients are excluded from the rest of this analysis.

Clinical characteristics of the 278 patients who underwent successful TTE-TAVI are listed in Table 1. The mean age of patients at the time of TAVI was 80.4 ± 10.0 years. Patients were divided into three groups according to the presence of severe sleep apnea (n=2) or class IV heart failure (n=3). The remaining 19 patients were not candidates for MAC sedation due to severe sleep apnea (n=2) or class IV heart failure (n=3). There were no significant clinical differences between these 19 patients and the TTE-TAVI cohort. Two of the 19 patients died prior to discharge, one as a result of acute respiratory failure 48 h post TAVI and the other as a result of multi-organ failure from vasodilatory shock. There were no complications of TOE or general anesthesia in these patients, and these 19 patients are excluded from the rest of this analysis.

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82.1 ± 7.3 years, and 52.5% (n = 146) were female. The mean Society of Thoracic Surgeons (STS) score was 6.3% ± 3.7%. All patients underwent TAVI through transfemoral access. We implanted the Medtronic EVOLUT R valve (Minneapolis, MN, USA) in 258 patients (92.8%), Medtronic CoreValve in 18 patients (6.5%), and Edwards Sapien Valve (Edwards Lifesciences, Irvine, CA, USA) in 2 patients (0.7%). Seventeen patients (6.1%) underwent TAVI for failing bioprosthetic aortic valve replacement (‘valve-in-valve’); the remaining 261 (93.9%) patients underwent TAVI for severe calcific stenosis of the native aortic valve. There were no intraprocedural deaths. There were 4 patients who suffered a cerebrovascular accident during hospitalization (1.4%). Five patients (1.8%) died during TAVI hospitalization (Table 2).

Pre-procedure, TTE-TAVI procedure (procedural echo), and 24-h post-procedure (24-h echo) TTE images were reviewed for overall image quality (Fig. 1). For the procedural echo, TTE image quality was excellent in 7 (2.5%) cases (Fig. 2), good in 136 (48.9%) cases, fair in 106 (38.1%) cases and poor in 29 (10.4%) cases. In 17 valve-in-valve procedures, image quality was excellent in 1 patient, good in 8 patients and fair in 8 patients. The pre-procedure images were acquired at multiple echocardiography laboratories; in 240 (86.3%) patients, these images were available for review. Excellent image quality was noted in 13 (5.4%) patients, good image quality in 117 (48.8%) patients, fair image quality in 90 (37.5%) patients and poor image quality in 20 (8.3%) patients. In the 240 patients with pre-procedure images available, there was no significant difference in the rate of poor image quality for pre-procedural TTE vs procedural TTE, and poor pre-procedural TTE image quality did not predict poor procedural image quality (7.2% vs 10.4%, P = 0.150). Subjects with body surface area ≥ 2.0 m² were more likely to have procedural image quality rated as poor (OR: 2.63, P = 0.012). The 24-h echo, performed in the hospital by the same dedicated sonographer group, was noted to have excellent image quality in 6.5%, good in 59.7%, fair in 30.0% and poor in 4.0%. As expected, post-TAVI echo quality was better than procedural echo (P < 0.001). We hypothesize this is due to the improved image quality in patients who, post 24-h TAVI, were now able to lie in the left lateral decubitus position. There were no statistically significant differences in image quality between pre-TAVI echo and procedural echo or pre-TAVI echo and post-TAVI echo. More patients had fair or better image quality on the 24-h echo than the procedural echo (96.0% vs 89.6%, P ≤ 0.001), but overall image quality was high in both procedural and 24-h echoes.
We next examined discrete characteristics of TTE images during procedural echo (Fig. 3). Parasternal TTE images were optimal in 221 (79.5%), adequate in an additional 50 (18.0%) cases, and suboptimal in only 7 (2.5%) cases. In those 7 cases with suboptimal parasternal TTE images, apical images were of optimal quality in 3 cases, adequate quality in 3 cases and suboptimal quality in 1 case. In this 1 case in which both parasternal and apical views were suboptimal, subcostal imaging was used. Apical TTE images were optimal in 171 (61.5%) cases, adequate in 80 (28.8%) cases and suboptimal in 27 (9.7%) cases. The valve was interrogated after deployment. Stent depth was visualized optimally in 260 (93.5%) cases, adequately in 12 (4.3%) cases and suboptimally in 6 (2.2%) cases. Stent shape was visualized optimally in 230 (82.7%) cases, adequately in 38 (13.7%) cases, and suboptimally in 10 (3.6%) cases. Valve leaflets were optimally visualized in 45 (16.2%) cases, adequately visualized in 45 (16.2%) cases and suboptimally visualized in 188 (67.6%) cases. Transvalvular regurgitation was used as a surrogate for abnormal leaflet motion – in only two cases was trace transvalvular regurgitation visualized, and in only 1 case was trace transvalvular regurgitation noted again at 24-h echo. Body surface area ≥2.0 m² was associated with less than optimal apical views (OR: 1.809, P = 0.024), less than optimal parasternal views (OR: 2.65, P = 0.001) and less than optimal color-flow Doppler (OR: 1.93, P = 0.041).

Both TTE and invasive hemodynamics were used in the assessment of need for post-deployment stent ballooning (n=23, 8.3%) due to PVL and/or stent underexpansion. During the procedure, dynamic LVOT or midventricular obstruction developed in 7 cases and was noted, quantified and treated. TTE also was able to recognize deep implant of the TAVI stent with significant transvalvular aortic regurgitation in 2 cases (0.7%), necessitating a second...
valve with resolution of transvalvular regurgitation. In 1 case, right ventricular function was visualized to be severely decreased post valve deployment – this patient was found to have a right coronary artery obstruction.

TTE adequately recognized new pericardial effusion in 3 (1.1%) cases. No case required TOE conversion for image quality; in 1 case, TOE was performed after the patient was intubated by the anesthesiologist for repair

Figure 3
Stacked bar graph of imaging characteristics of procedural echocardiography (n=278).

Figure 4
Transthoracic echocardiography visualized intraprocedural pericardial effusion and tamponade – fair image quality. (A) Transthoracic parasternal long-axis view demonstrating severe calcific aortic stenosis and no pericardial effusion. (B) Immediately after transcatheter aortic valve implantation, pericardial effusion was visualized (orange arrow). (C) This pericardial effusion was redemonstrated on parasternal short-axis view and appeared larger; the left ventricle was demonstrated to be underfilled. This combined with hypotension required emergency endotracheal intubation and sternotomy. A pericardiocentesis was performed and a wire perforation was identified in the left ventricle and repaired. Despite fair image quality, trace paravalvular regurgitation was identified on TTE. (D and E) This same jet of paravalvular regurgitation was also noted on TOE images in short-axis and long-axis (F) esophageal views (green arrows).
of left ventricular perforation and tamponade after TTE adequately diagnosed acute pericardial effusion. In that patient, a mild PVL jet was visualized by TTE and subsequently visualized again by TOE – no other PVL jets were noted with TOE (Fig. 4).

We then reviewed color-flow Doppler quality and PVL assessment (Fig. 5). Color-flow Doppler was optimal in 230 (82.7%) cases, adequate in 45 (16.2%) cases and suboptimal in 3 (1.1%) cases. In 276 patients, PVL was assessed by procedural TTE. PVL was assessed in both parasternal and apical views, with heavy emphasis placed on the short-axis parasternal LVOT view to determine the circumferential extent of the jet. In 7 (2.5%) patients with suboptimal parasternal views, this short-axis view was not obtainable and PVL assessment was made from apical views. No more than mild PVL was seen in 254 (91.4%) patients. In 2 cases, PVL was unable to be assessed due to poor image quality; in those 2 cases, assessment of PVL was performed by fluoroscopy, aortic root injection and invasive hemodynamics. PVL was judged, by these markers, to be no more than mild. On follow-up TTE 24 h later, both these patients were noted to have no more than mild PVL, and this persisted at 1-month follow-up. Of the 254 patients with no more than mild PVL in the procedural echo, only 1 patient was noted to have moderate PVL on 24-h echo and the 1-month echocardiogram (1-month echo); as the patient was asymptomatic, this patient was followed clinically with no intervention performed. This patient had overall fair image quality on procedural echo, but the study was limited only to adequate parasternal views and apical views were unobtainable. The remaining patients were all noted to have no more than mild PVL at 24 h. There were 39 (7.9%) patients in whom a follow-up 1-month echo was not available for review; in the patients for whom 1-month echocardiography was available, all had no more than mild PVL at 1-month follow-up. There were 22 patients diagnosed with moderate PVL during the procedure. By 24 h, 6 cases had no more than mild PVL and 16 cases had moderate PVL. In 1 patient with a valve-in-valve procedure of aortic homograft, moderate PVL was identified; this patient was symptomatic and underwent repeat TAVI 7 days later, with moderate PVL after the second procedure. At 1-month follow-up, only 6 patients were noted to have persistent moderate PVL. On univariate analysis, poor image quality during the procedure was not associated with moderate PVL ($P=0.264$).

**Discussion**

We describe our results using TTE for intraprocedural guidance during TAVI in 278 patients at a highly experienced TAVI center using current generation valves. We are the first study to systematically review the image quality and imaging characteristics of TTE-TAVI. As we have demonstrated, in 89.6% of cases, TTE image quality was fair or better. Stent depth and frame shape were visualized adequately in the majority of patients. While leaflets were not clearly visualized in the majority of patients, the presence of leaflet dysfunction could be inferred from the presence of transvalvular regurgitation. In 99% of patients, the use of TTE intraprocedurally did not impair our ability to accurately assess PVL. In the long term, our procedural assessment of PVL correlated highly with 24-h echo and 1-month follow-up echo assessment.
of PVL. There were no instances of TOE conversion due to poor image quality. In our highly experienced TAVI center, there were few procedural complications, no intraprocedural deaths and a high rate of survival to hospital discharge.

In our study, the majority of TAVI valves implanted were the EVOLUT R valve (92.8%), an improvement upon the earlier generation of the Medtronic CoreValve system that is resheathable and repositionable. Our procedural results are similar to the initial experiences with EVOLUT R; in a case series of 241 patients (8), PVL was no more than mild in 94.7% of patients at 1-month follow-up. In that study, 188 (80.7%) cases were performed with general anesthesia and TOE guidance. As in our experience, procedural complications were low: only 3 cases required a second valve (in our study 1 case), coronary occlusion was seen in 1 case (in our study 1 case) and post-balloon dilation occurred in 33.2% (in our study only 8.3%). In a similar study of 264 patients with EVOLUT R, PVL was no more than mild in 92.3% (9), procedural complications were also low (cardiac tamponade 0.4%), there were no procedural deaths and 1-month follow-up demonstrated good clinical outcomes. Of note, in that study, 39.8% of procedures were performed with conscious sedation (although the proportion of those with TTE or TOE was not commented upon in the study). These two studies demonstrate overall lower rates of PVL and procedural complications compared with the older generation CoreValve (10). We demonstrated that TTE performed by a dedicated team is adequate to identify these complications and assess PVL in this era of overall lower complications.

In this new era of safer TAVI, the advantage of a TTE-TAVI strategy is that it is less invasive, a key component in the trend toward a ‘minimalist TAVI’ strategy (11, 12) that is predominantly driven by the avoidance of general anesthesia. These monitored anesthesia sedation or conscious sedation states have been shown to correlate with shorter procedure times and better patient outcomes, particularly in patients with comorbidities (13, 14, 15). Although TOE with conscious sedation has been employed (16), it is not the ideal strategy given the risks of esophageal intubation and aspiration in patients without a protected airway. The use of TOE in non-intubated patients is documented in guidelines (17), yet, is still controversial in practice. Thus, given the reluctance to perform TOE in non-intubated patients, the central issue of TTE-TAVI then becomes the trade-off of image quality and sedation. In experienced hands, where expertise in TAVI and echocardiography are high, our data suggest that TTE image quality is more than adequate for current generation valves.

TOE vs TTE in the guidance of TAVI has never been compared in a prospective randomized study. There is only 1 published study to date that focused on clinical outcomes of TTE-TAVI (18) in comparison to a TOE-TAVI cohort. In that study, 454 patients were implanted with the balloon-expandable Edwards Sapien Valve. They were compared to a retrospective cohort of patients who underwent TOE with general anesthesia. The authors found that TTE-TAVI was associated with greater post-deployment balloon inflation and worse outcomes than the TOE-TAVI cohort. There are important differences between this study and our study. First, that study population received all balloon-expandable valves. The nature of self-expandable valves is that there is an expectation that the valve stent will expand more in 24 h, and that PVL, when seen during the procedure, may improve at 24 h. The stent depth and stent frame then become of great concern, and these were both seen quite well in our study. We also used fluoroscopy for decision-making on stent placement, as opposed to echocardiography, as in the other study. If echocardiography is used for stent position prior to deployment, then TTE would be expected to be inferior to TOE – as we have demonstrated, parasternal images are optimal only in 79% of cases. Finally, their overall rates of post-deployment balloon inflation and procedural outcomes were much higher than those in our study.

Lastly, our study highlights the importance of a dedicated echocardiography team, comprising interventional echocardiographers and cardiac sonographers with special training and expertise in TTE-TAVI. As expected, larger body surface area (BSA>2.0m²) was associated with overall poorer image quality and suboptimal parasternal, apical and color Doppler views. Nonetheless, pre-procedure TTE did not predict the quality of procedural echo, and procedural echo was only of poor quality in a small percentage of cases. One would have expected a higher percentage of poor-quality studies during the procedure because these patients were imaged in the supine position as opposed to traditional left lateral decubitus position. Yet, despite this limitation, we did not observe a significant degradation in image quality during the procedure. This is likely owing to the fact that pre-procedural echo was performed with a heterogeneous group of sonographers on a variety of ultrasound platforms, whereas TTE-TAVI was performed with only a small group of dedicated sonographers specially trained for interventional echocardiography.
Study limitations

There is no randomized study that has examined TOE vs TTE for procedural guidance of TAVI. Our study is limited by the retrospective nature of review. We did not report interobserver and intraobserver variability in this retrospective study. We elected not to compare TTE-TAVI patients to a historic cohort of TOE-TAVI patients, as both technology and our clinical expertise improved from the time we transitioned from TOE to TTE for intraprocedural guidance.

Conclusions

In experienced hands and using the latest generation of TAVI stents, TTE during the TAVI procedure had fair or better image quality in 89.6% of cases and adequately conveyed information on TAVI characteristics, PVL and procedural complications compared with 24-h and 1-month echocardiograms. Dedicated TTE is adequate intraprocedurally when performed by specialized sonographers and dedicated cardiologists in a highly experienced center.

Declaration of interest

The authors declare there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

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