JACC: CARDIOVASCULAR IMAGING
VOL. 1, NO. 1, 2008

ISSN 1936-878X/08/$34.00
PUBLISHED BY ELSEVIER
DOI:10.1016/j.jcmg.2007.09.004

Role of Echocardiography in Percutaneous Aortic Valve Implantation

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OBJECTIVES This study was designed to investigate the usefulness and limitations of echocardiography in optimizing the outcome of percutaneous aortic valve implantation.

BACKGROUND Percutaneous aortic valve implantation is an emerging technique that has the potential to revolutionize the treatment of aortic valve disease. To date, however, the technique has been limited by technical constraints. Precise positioning of the valve is essential to minimize the potential for paravalvular regurgitation or device migration. Initial experience with device placement utilized fluoroscopic guidance only.

METHODS Candidates for percutaneous aortic valve implantation were evaluated with transthoracic echocardiography (TTE) to assess aortic annular dimension and aortic valve hemodynamics. Fifty consecutive patients were deemed suitable for percutaneous aortic valve implantation. Seventy-four percent (37 of 50) of patients underwent transesophageal echocardiography (TEE) during the procedure.

RESULTS Eighty-six percent (43 of 50) of patients had successful implantation, of which 77% (33 of 43) had TEE. Transthoracic echocardiography was used to determine annular dimension and was useful in guiding correct device sizing. Transesophageal echocardiography was able to successfully guide device implantation in 97% (33 of 34) of patients in whom the native valve was crossed with the percutaneous heart valve. Transesophageal echocardiography was used for the early detection of paravalvular aortic regurgitation (AR) and complemented fluoroscopy in the detection of complications. Additional balloon dilatation of the percutaneous heart valve was performed in 12 patients because of significant paravalvular AR, with 7 showing improvement in AR grade. After the procedure, early outcomes were evaluated using TTE. All patients in whom the device was successfully placed (43 of 50) had improvement in their aortic stenosis. Paravalvular AR, although present in many patients, is usually mild and has not emerged as a significant problem.

CONCLUSIONS Echocardiography has an important role in case selection, in guiding device placement, and in detecting complications of percutaneous aortic valve implantation. (J Am Coll Cardiol Img 2008;1:15–24) © 2008 by the American College of Cardiology Foundation

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Manuscript received July 10, 2007; revised manuscript received September 20, 2007, accepted September 28, 2007.

As the population ages, the timely and effective treatment of calcific aortic stenosis will assume increasing importance. Until recently the only effective treatment for aortic stenosis has been cardiac surgery and aortic valve replacement. Although percutaneous balloon aortic valvuloplasty may be effective as a palliative procedure, it often produces a suboptimal hemodynamic and clinical result and cannot be regarded as a definitive therapy (1,2).

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Building on the seminal work of Cribier et al. (3), successful implantation of percutaneous heart valves (PHVs) with excellent clinical and hemodynamic outcomes has been reported at our institution (4). Transthoracic echocardiography (TTE) was routinely used to guide case selection and in the evaluation of outcomes after PHV implantation. Transesophageal echocardiography (TEE) has emerged as a vital adjunct to fluoroscopy in guiding PHV deployment.

In this study we report on the role of echocardiography in patient selection, device sizing, device placement, and evaluation of outcome in patients undergoing this new technique.

ABBREVIATIONS AND ACRONYMS

AR = aortic regurgitation

PHV = percutaneous heart valve

TEE = transesophageal echocardiogram/echocardiography

TTE = transthoracic echocardiogram/echocardiography

METHODS

Patients. Fifty patients underwent PHV implantation at our institution between January 6, 2005 and May 29, 2006. The median age was 81 years (range 62 to 94 years), and 30 of 50 patients (60%) were male. The procedure was approved for compassionate clinical use by the Therapeutic Products Directorate of Canada.

Percutaneous aortic valve implantation. The technique of transfemoral percutaneous aortic valve implantation and valve design has been described elsewhere (4). In brief, the aortic valve was approached from a retrograde direction and the PHV was deployed by rapid balloon inflation. If significant paravalvular aortic regurgitation (AR) was found immediately after deployment, further balloon inflations were performed.

Preliminary TTE assessment. Transthoracic echocardiography was performed on all patients before the procedure. Images were recorded on a Philips Sonos 5500 machine (Bothell, Washington) and the images were stored and archived in digital format. Harmonic imaging was used in all instances. Offline image analysis and measurement was performed using a Philips Xcelera digital archiving and reporting system. A standard transthoracic examination was performed with special attention being paid to the aortic annular dimension, severity of aortic stenosis, and distribution and severity of valve calcification.

Measurement of the aortic annulus was performed using 2-dimensional imaging in a zoomed-up parasternal long-axis view at the point of insertion of the right and noncoronary aortic cusps into the aortic annulus (Fig. 1A). Transesophageal echocardiography was used when poor imaging meant that a reliable estimate could not be made. Measure-

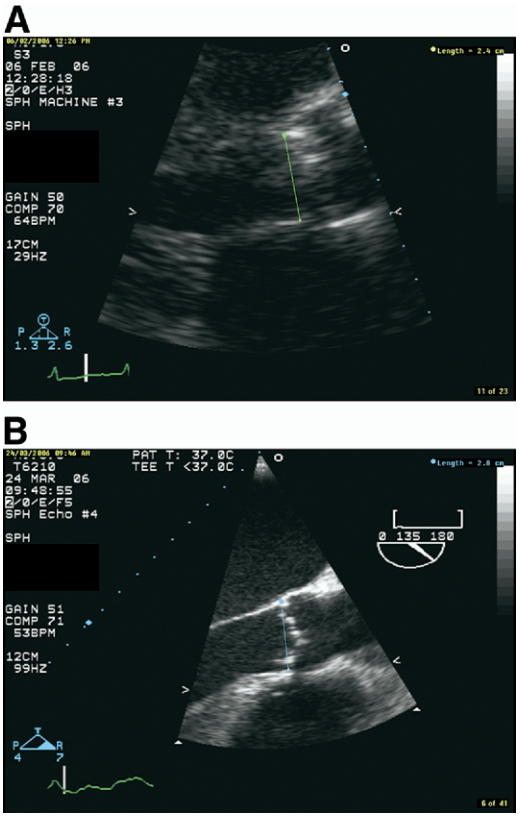

Figure 1. Aortic Annulus Dimension Assessed by Both TTE and TEE

(A) Accurate transthoracic echocardiography (TTE) measurement of the aortic annulus is essential to determine a patient's suitability for percutaneous heart valve (PHV) placement. Patients are deemed unsuitable if the aortic annulus is either too large (>26 mm) or (rarely) too small. The TTE image shows a zoomed-in parasternal long-axis view of the aortic annulus. The aortic annulus measures 24 mm. **(B)** Before PHV deployment, transesophageal echocardiography (TEE) is used to check the aortic annulus measurement obtained by TTE. A difference of up to 4 mm between the TTE and the TEE annulus measurements can occur and may lead to a change in device size. Transesophageal echocardiography long-axis image of the patient as shown in **panel A** shows the aortic annulus measured at 28 mm.

ments of left ventricular size and function, wall thickness, and pulmonary artery pressure were noted. Valvular regurgitation was evaluated according to published guidelines (5).

Early TTE assessment after device deployment. A complete TTE examination was performed on all patients within 1 week of device implantation and before hospital discharge. Specifically, PHV hemodynamics, post-deployment complications, and AR grade were evaluated. Transaortic pressure gradient and aortic valve area were determined.

Aortic regurgitation was assessed using color Doppler, pressure half-time, vena contracta width, and flow reversal techniques. Aortic regurgitation was graded as follows: zero or trace, mild, moderate, and severe. Aortic regurgitation was classified as paravalvular, transvalvular, or both. The parasternal short-axis view of the aortic valve was especially useful in this regard. There are limited published data on grading paravalvular regurgitation, and the assessment scheme we have used is similar to that used by Kapur et al. (6). Grading was based primarily on the height of the regurgitant jet in the parasternal long-axis view and the circumferential extent of the jet in the short-axis view. When both valvular and paravalvular AR were present, AR was expressed as an overall grade. Left and right ventricular function, pulmonary artery pressure, and grade of mitral and tricuspid regurgitation were determined.

TEE imaging and guided valve deployment. Transesophageal echocardiography was performed in 74% (37 of 50) of cases and is now performed routinely. The TEE probe was introduced under general anesthesia during the introductory phases of the procedure. The images were available to the interventional cardiologist on a slave monitor located alongside the fluoroscopy screens. The aortic valve was imaged, and measurements of the aortic annulus (Fig. 1B) and left ventricular outflow tract were made. Aortic regurgitation was quantitated by color Doppler. Careful attention was paid to anatomical landmarks such as the distribution of aortic valve calcification and ectopic calcification of the basal portion of the anterior mitral leaflet and annulus because these were found to be useful in optimal placement of the prosthesis. Left and right ventricular systolic function, regional wall motion abnormalities, and mitral or tricuspid regurgitation were noted before and after valve deployment. In most cases, the aortic arch was evaluated for the presence of severe aortic arch atheroma.

For the deployment part of the TEE examination, the long-axis (130°) transesophageal view was used. Long digital loops of 10 to 15 beats were used to capture the moment of valve deployment. Once the device was deployed, correct positioning was verified and any AR classified as valvular or paravalvular. Balloon re-dilatation of the valve was performed if there was more than mild paravalvular regurgitation. After removal of the deployment catheter and guidewire, the degree of AR was reassessed. Limited Doppler estimation of valve gradients via the transgastric window was performed when image quality permitted and when an acceptable angle for Doppler interrogation of the aortic valve was available.

Statistics. Success rate with and without TEE was compared using a Fisher exact test. The general estimating equation was used to assess for any changes in the same parameters at 1, 6, and 12 months. Transesophageal echocardiography and TTE AR severity was compared using the Wilcoxon signed rank test. The Bland-Altman plot was used to compare aortic annular measurements by 2

Table 1. Core TTE Parameters for Study Cohort Recorded at Baseline and Follow-Up

Characteristic	Baseline (n = 50)	Valve Implanted (n = 43)	Before Discharge (n = 42)	1 Month (n = 38)	6 Months (n = 30)	12 Months (n = 17)
Aortic valve area, cm2, mean ± SD	0.6 ± 0.2	0.6 ± 0.2	1.7 ± 0.4*	1.7 ± 0.4	1.6 ± 0.5	1.6 ± 0.3
Mean AVG, mm Hg, mean ± SD	46 ± 17	46 ± 17	11 ± 5*	11 ± 4	11 ± 5	14 ± 5
LV ejection fraction, %, median (Q1, Q3)	60 (50, 65)	60 (45, 65)	60 (60, 65)*	65 (60, 65)	64 (56, 65)	60 (55, 65)
Mitral regurgitation, median (Q1, Q3)	1 (0, 2)	2 (1, 2)	1 (0, 2)†	1 (0, 2)	1 (1, 1)	1 (0, 1)
Aortic regurgitation, median (Q1, Q3)	0 (0, 1)	0 (0, 1)	1 (0, 1)‡	1 (0, 1)	1 (0, 1)	1 (0, 1)
Severe [4] (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Moderate [3] (%)	3 (6)	3 (7)	3 (7)	5 (13)	4 (13)	3 (18)
Mild [2] (%)	21 (42)	17 (40)	21 (50)	19 (50)	18 (60)	9 (53)
None/trivial [0,1] (%)	25 (50)	22 (51)	18 (43)	12 (32)	8 (27)	5 (29)

Significant improvement in aortic valve area and mean AVG were noted at pre-discharge echocardiogram. These improvements were maintained at 1, 6, and 12 months of follow-up. Numerical grading of valvular regurgitation is as follows: 0 = none, 1 = trivial, 2 = mild, 3 = moderate, and 4 = severe. *$p < 0.0001$; †$p = 0.01$; ‡p = not significant.
AVG = aortic valve gradient; LV = left ventricular; SD = standard deviation; TTE = transthoracic echocardiography.

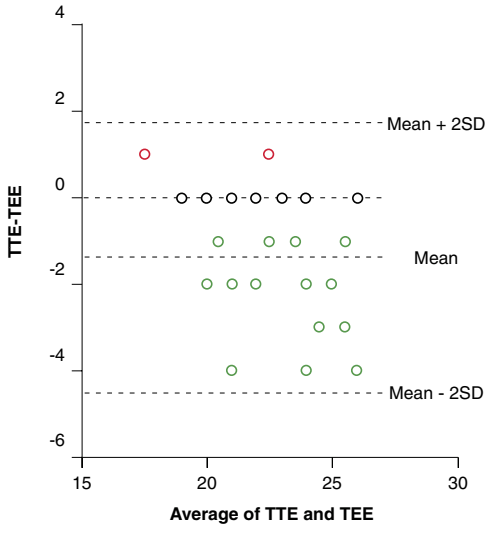

Figure 2. Bland-Altman Plot Illustrating the Difference Between the Aortic Annular Dimension Determined by TTE and TEE

Important differences may exist between aortic annulus size as determined by either TTE or TEE. The **red circles** indicate larger dimensions by TTE; the **black circles** indicate agreement; the **green circles** indicate larger dimensions by TEE. Annular dimension was determined by TTE before PHV implantation and TEE dimension at time of implantation. Abbreviations as in Figures 1 and 4.

different methods, TEE and TTE. A 2-sided p value <0.05 was considered statistically significant. Statistical analyses were conducted using SPSS version 13.0 (SPSS Inc., Chicago, Illinois).

RESULTS

Assessment by TTE before device implantation. Baseline echocardiographic parameters are shown in Table 1. The column "Valve Implanted" shows baseline values for all patients in whom a PHV was implanted. All patients had severe aortic stenosis with a valve area of ≤ 0.75 cm^2. Median left ventricular ejection fraction was 60% (interquartile range 50% to 65%), and median mitral regurgitation was graded mild (interquartile range trivial to moderate). Mean transthoracic aortic annulus dimension was 22 ± 2 mm (range 18 to 26 mm).

TEE assessment and guided valve deployment. The overall immediate success rate was 86% (43 of 50). Valve deployment was successful in 89% of cases (33 of 37) in which TEE was used. The success rate in patients without procedural TEE was 77% (10 of 13) (not significant, $p = 0.36$). Procedural failure was due to inability to cross the native aortic valve (after valvuloplasty) in 2 cases, inability to pass the device through the aortic arch in 1 case, and malpositioning in 1 case. There were no complications related specifically to TEE.

Device sizing and annular measurement by TEE. Thirty-three of 50 patients in the series had successful TEE-guided valve deployment. The differences between aortic annular dimensions measured by TEE and TTE are shown in the Bland-Altman plot in Figure 2. The mean difference in aortic annulus dimension was 1.36 mm, with the annulus dimension by TEE yielding larger values than TTE. Within 2 standard deviations of this mean, the differences between these 2 methods ranged between −4.48 and +1.75 mm. A difference of up to 4 mm between the TTE and the TEE annular measurements can occur and may lead to a change in device size.

Preliminary suitability for this procedure has been based on TTE aortic annulus measurement of 26 mm or less. One of these patients was found to have an aortic annulus dimension of 28 mm at TEE, and successful device deployment was undertaken in this patient with acceptable results.

TEE and device deployment. Transesophageal echocardiography was useful as an adjunct to fluoroscopy in guiding balloon dilatation of the aortic valve and to assess any subsequent improvement in leaflet mobility. During right ventricular pacing, there should be no visible ventricular contraction if capture is good and pacing rate is appropriate. This can be verified with TEE before valve deployment.

Transesophageal echocardiography was useful in positioning the aortic valve in most (33 of 34) patients. Lack of utility was due to inadequate native valve and PHV visualization. This could usually be overcome with manipulation of the probe position and angulation. Best imaging was in general obtained in those patients with less calcified aortic valves, a situation in which fluoroscopy is least helpful. Imaging was less useful in patients in whom acoustic shadowing made clear visualization of the stented prosthesis on the balloon and its position in relation to the aortic annulus difficult. Good coaxial alignment of the guidewire and subsequent direction of the catheter toward the aortic orifice was important to the success of the procedure. Transesophageal echocardiography was useful in some instances in ensuring that the steerable catheter was directed toward the aortic orifice, and not directed toward a commissure.

Once the PHV was mounted on the deployment balloon, careful imaging was required to identify the precise location of the valve stent in relation to the

deployment balloon. Incremental manipulation of TEE probe tip position and angle and selection of the highest possible frequency are used to optimize the echocardiographic image. Every attempt was made to show both the ventricular and aortic ends of the stent in one imaging plane. This was not invariably possible. For this reason, it was important for the echocardiographer to be aware of the stent length so as to optimize positioning in relation to the aortic annulus and leaflets. The stent was identified as an echogenic rectangular structure seen in sharp profile to the deployment balloon. In particular, the identification of the echogenic right angle or "shoulder" that corresponded to the ventricular or aortic edge of the stent was a clear indication that the stent has been correctly differentiated from the underlying balloon (Fig. 3A). With practice, it was possible to consistently identify the ventricular and aortic ends of the stent, as long as the degree of valve calcification did not cause excessive shadowing.

The PHV can move up to 2 to 4 mm in the direction of the ascending aorta with balloon inflation and deployment. The optimal position of the stented prosthesis (before balloon deployment), therefore, seems to be when the ventricular end of the stent is positioned approximately 2 to 4 mm below the most ventricular portion of the native aortic leaflets and annulus. This usually corresponds to a point just ventricular to the hinge point of the anterior mitral leaflet. The aortic end of the stent should slightly overlie the upper limit of the native aortic leaflets. The PHV thus lies within the native aortic leaflets, and during deployment the native aortic leaflets are compressed between the valve stent and the wall of the aortic root (Fig. 3B), with the fabric cuff of the PHV aligned within the aortic annulus. After deployment, the aortic end of the valve stent should be below the level of the coronary ostia. The ventricular end of the valve stent should not interfere with anterior mitral leaflet function. For best results, the valve stent should be closely apposed to the aortic annulus (Fig. 3C). The valve is deployed when both echocardiographer and interventionist agree that position is acceptable.

Complications. EARLY DEVICE MIGRATION. Device migration was noted in 2 patients. In the first instance, TEE imaging was not used and the device was deployed too aortic with respect to the aortic annulus. In the second instance, TEE imaging was used, however, the presence of a stented mitral valve prosthesis interfered with the deployment process. In both instances, the PHVs were subsequently

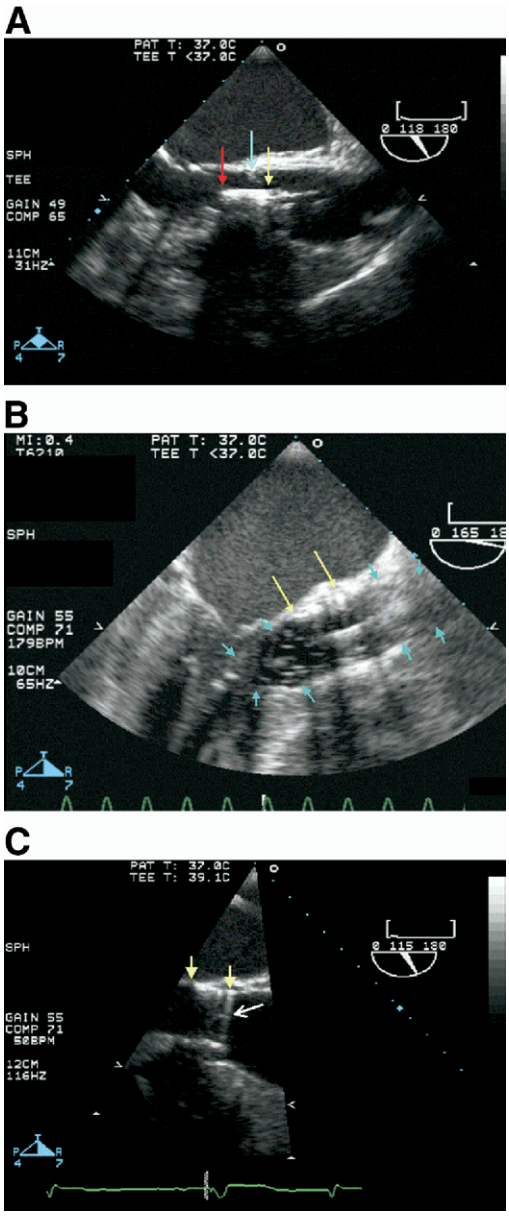

Figure 3. TEE-Guided PHV Positioning and Deployment

Good awareness of the echocardiographic appearance of the undeployed PHV (stent) and its relation to the deployment catheter and balloon is critical to correct device positioning. **(A)** Transesophageal echocardiography long-axis view showing satisfactory stent position before deployment. The undeployed PHV is identified as an echogenic rectangular structure, which is seen in contrast to the larger and less echodense balloon. The ventricular **(red arrow)** and aortic **(yellow arrow)** ends of the stent are indicated in relation to the native aortic valve **(blue arrow)**. Online Video 1 shows the ideal position for the stented PHV prior to deployment. **(B)** Long-axis view at the moment of balloon deployment of the PHV. The **blue arrowheads** indicate the balloon and **yellow arrows** the prosthesis. Online Video 2 shows deployment of the PHV by rapid balloon inflation. The final appearance of the deployed PHV is seen in **panel C**. The **yellow arrows** indicate the stent and the **white arrow** the prosthetic valve leaflet. The fully deployed PHV is shown in the short-axis view in Online Video 3. Online Video 4 shows imaging of the deployed prosthesis in the long-axis view. The prosthesis is in good position and no aortic regurgitation is seen. Abbreviations as in Figure 1.

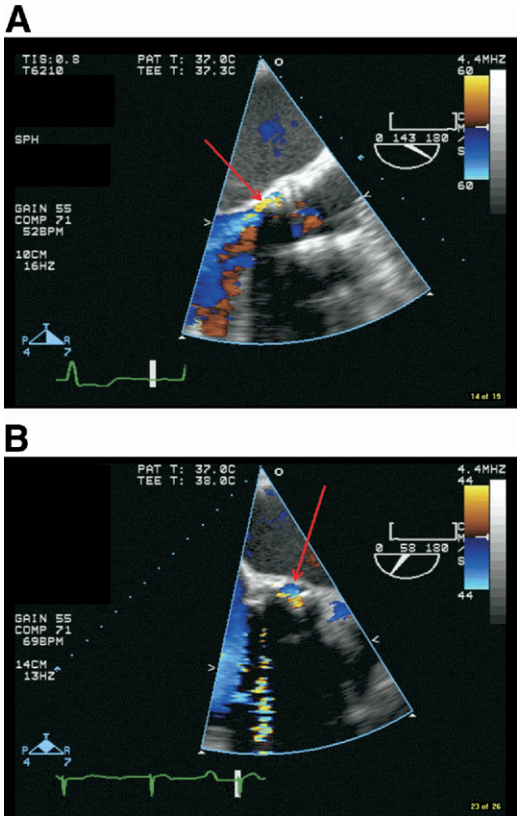

Figure 4. Early TEE Assessment of Paravalvular AR After PHV Deployment

Early assessment of paravalvular AR is an indicator of procedural success but may also help to determine the need for subsequent balloon dilatation of the PHV. **(A)** Transesophageal echocardiography showing mild paravalvular regurgitation **(red arrow)** in the long-axis view. **(B)** TEE showing mild paravalvular regurgitation **(red arrow)** in the short-axis view. It is the short-axis view that most reliably distinguishes paravalvular AR from transvalvular AR, especially if the vena contracta of the paravalvular jet is out of plane in the long-axis view. Online Video 5 shows a short-axis view of AR following PHV deployment. Paravalvular AR is seen at the 3 o'clock position along with a smaller jet of transvalvular AR. AR = aortic regurgitation; other abbreviations as in Figure 1.

withdrawn to the aortic arch and redeployed. Both patients remain well over 1 year later.

EVALUATION OF HYPOTENSION. In the presence of hypotension, TEE provides a rapid early assessment of changes in global left ventricular systolic function, mitral regurgitation, and the presence or absence of regional wall motion abnormalities during the critical period immediately before, during, and after valve deployment. Global left ventricular dysfunction, most likely due to global myocardial ischemia, has occasionally been noted immediately before PHV deployment. This is generally seen as an indication for rapid PHV deployment. No instances of significant pericardial effusion have been seen; however, the echocardiographer is periodically called on to rule out this diagnosis.

MITRAL REGURGITATION. Transient worsening of mitral regurgitation has been noted in 2 instances immediately after valve deployment. In both cases, this seemed to be related to the use of right ventricular pacing, which is sometimes needed to treat AV block or bradycardia after valve deployment. No direct mechanical effect on the mitral valve of the deployed PHV has been seen.

EARLY TEE ASSESSMENT OF AR. Of the patients who underwent successful TEE-guided PHV deployment, 97% (32 of 33) had technically adequate assessment of their AR. Some degree of AR was observed on TEE in 88% of patients (28 of 32) after successful deployment of the device, and examples are shown in Figures 4 and 5. Paravalvular AR was

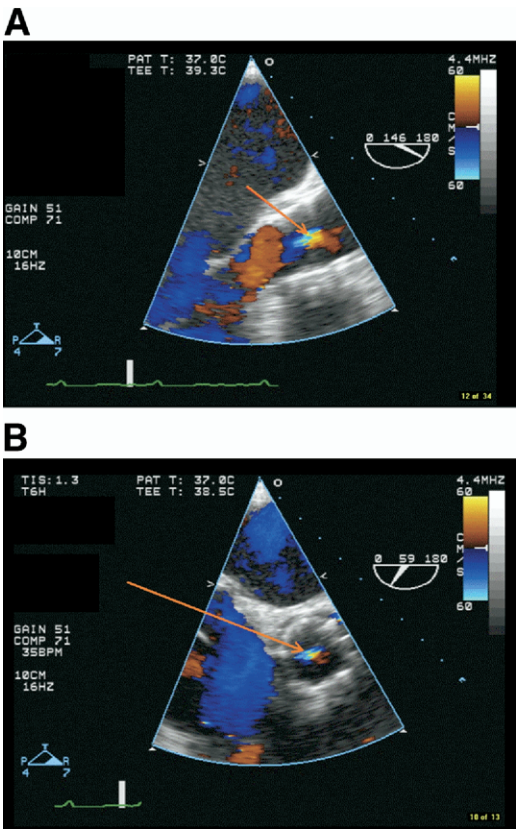

Figure 5. Early TEE Assessment of Transvalvular AR After PHV Deployment

Immediately after PHV deployment, paravalvular AR must be distinguished from transvalvular AR. The short-axis views may be especially useful in this instance. Transesophageal echocardiography showing mild valvular regurgitation **(red arrow)** in the long-axis **(A)** and short-axis **(B)** views. Abbreviations as in Figures 1 and 4.

observed on TEE in 84% of cases (27 of 32). One patient had isolated valvular regurgitation.

Early grading of AR severity by TEE was useful in guiding subsequent management. In 13 patients, it was judged that significant paravalvular AR was present immediately after valve deployment, and additional balloon dilatation of the PHV was performed in 12 of these. One patient with moderate paravalvular AR early in the series did not undergo additional balloon dilatation. Of the patients who underwent additional balloon dilatation, 7 of 13 had improvement of paravalvular AR by at least 1 grade.

The results for overall TEE assessment of AR, at the end of the procedure, are presented in Table 2. Most patients (26 of 32, 81%) had mild or less AR at the conclusion of the case. No instances of severe AR were seen. The most common site of regurgitation is in relation to the posterior aspect of the stent; however, paravalvular jets may occur in any part of the circumference of the annulus.

In 1 instance, residual native aortic valve leaflet tissue was seen to prolapse into the PHV and interfere with leaflet motion, causing mild valvular AR, a complication that may have resulted from insufficient containment of residual native aortic tissue by the PHV, allowing redundant valve leaflet to interfere with prosthetic leaflet coaptation.

THROMBUS. Mobile echogenic material has been noted in relation to the deployed PHV on 2 occasions. Although we have assumed this to be thrombus, it would be difficult to differentiate this appearance from that of fragmented aortic leaflet material that had been inadequately contained by the PHV.

UNUSUAL COMPLICATIONS. Exuberant aortic leaflet calcium was displaced into the ostium of the left main coronary artery in 1 instance. Death from presumed myocardial ischemia occurred a few days after the procedure. This situation was not recognized at TEE but was visualized retrospectively on fluoroscopy and confirmed at autopsy. In another case there was fatal rupture of the descending thoracic aorta by the deployment assembly. In that instance, TEE was able to visualize the periaortic hematoma (Fig. 6).

TTE POST-DEPLOYMENT. Pre-discharge TTE was performed on 42 of 43 patients in whom the PHV had been successfully deployed. One patient died after successful deployment but before TTE could be performed. The PHV was well seated in all patients, and there were no instances of delayed device migration. There were significant improvements in aortic valve area and mean pressure gradient after successful valve deployment (Table 1). An example of a typical result is shown in Figures 7A and 7B.

Table 2. TEE Assessment of Aortic Regurgitation Immediately After PHV Implantation

Grade of Aortic Regurgitation by TEE (n = 32)*	Trivial	Mild	Moderate	Severe
Mixed aortic regurgitation (overall grade) (n = 14)	5	6	3	0
Isolated paravalvular regurgitation (n = 13)	2	8	3	0
Isolated valvular regurgitation (n = 1)	1	0	0	0
No aortic regurgitation (n = 4)	—	—	—	—

Most patients had mild or less aortic regurgitation, and no instances of severe aortic regurgitation were seen. *Aortic regurgitation not assessed in 1 patient.
PHV = percutaneous heart valve; TEE = transesophageal echocardiography.

Post-implantation TTE has shown favorable results with regard to AR in the majority of patients to date. Some degree of AR was present in 93% of patients (39 of 42) on the pre-discharge TTE but in most instances was trivial or mild. The results for TTE assessment of AR are presented in Table 1.

Overall AR grade was unchanged between the baseline pre-procedure TTE and the post-implantation TTE assessment ($p = 0.20$). In all 3 cases in which AR was moderate before valve implantation, AR severity decreased to trivial or mild.

AR GRADE BY PROCEDURAL TEE AND EARLY FOLLOW-UP TTE. A comparison of AR grade by procedural TEE and early follow-up TTE of the 31 patients with successful TEE-guided implantation

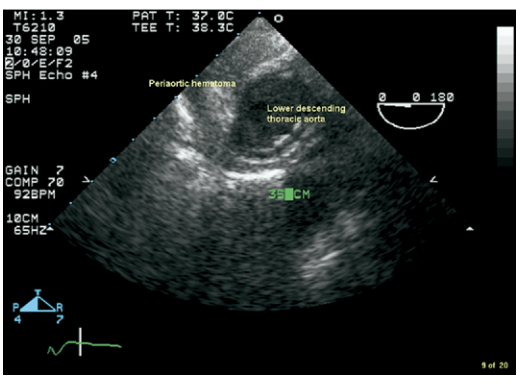

Figure 6. Periaortic Hematoma After Attempted PHV Deployment

Periaortic hematoma as a result of rupture of the lower descending thoracic aorta is an unusual complication of PHV deployment. In this instance the patient became hypotensive as the PHV assembly was being advanced through the abdominal and lower thoracic aorta. Contrast injection showed extravasation of dye, after which TEE was used to identify peri-aortic hematoma. Abbreviations as in Figure 1.

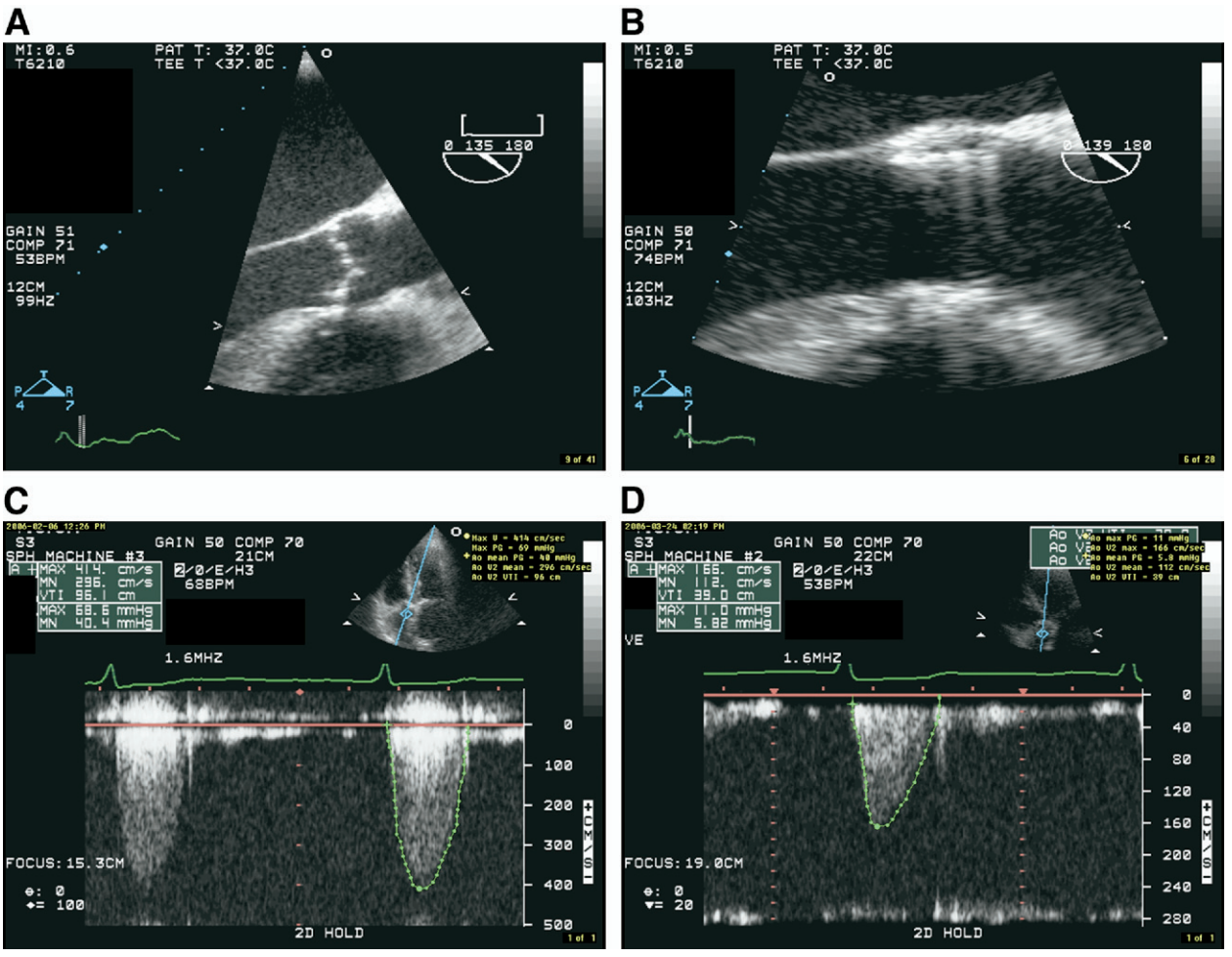

Figure 7. Early 2-Dimensional Appearances and Doppler Gradients After PHV Implantation

A PHV implantation has the potential to give excellent early morphologic and hemodynamic results. Transesophageal echocardiography long-axis views are shown before **(A)** and after **(B)** implantation of a PHV. Successful PHV implantation also leads to a marked early reduction in transaortic pressure gradient. Transaortic Doppler gradients in the same patient are shown before **(C)** and after **(D)** PHV implantation. Abbreviations as in Figure 1.

is presented in Figures 8A and 8B (1 successful TEE-guided case was excluded because of death before discharge TTE). Less valvular AR was observed at early follow-up TTE assessment than was present at post-implantation TEE ($p = 0.02$).

DISCUSSION

Aortic annulus measurement and device sizing. Transesophageal echocardiography has assumed an increasingly important role in the successful sizing and deployment of the PHV, and hence is critical to minimizing the potential for device migration, unacceptable AR, or ineffective treatment of the aortic stenosis. Correct sizing of the valve is critical to stability post-deployment and to minimizing the potential for paravalvular AR. The larger valve assembly may not be able to be advanced in the presence of marginal vascular access or may be unable to cross the aortic valve in the presence of a very small annular dimension. By comparison, significant undersizing of the PHV may result in device migration or in unacceptable paravalvular AR.

Measurement of the aortic annulus by TTE is an important consideration in initial patient selection. We deemed some patients unsuitable on the basis that their annular size was either too large or too small to accommodate a valve presently available; however, the proportion of the patient population with severe aortic stenosis that would be ruled out for PHV is likely to be small. After review by the core group, which included an interventional cardi-

ologist and 2 echocardiographers, fewer than 5 cases were deemed unsuitable for PHV implantation by echocardiographic criteria during the study period. This being said, we have empirically chosen the cut points for annulus dimension that we believe are unfavorable, so the true limits for the present technology remain undefined.

The disparity noted between the TTE and TEE measurements of aortic annulus size is of interest and may reflect acoustic blooming possibly exacerbated by use of harmonic imaging with TTE. Although preliminary suitability for implantation was based on TTE annular dimension, the PHV was sized according to the TEE annulus dimension, taking into account patients with borderline vascular access that may only have permitted the use of a smaller device. In general, the 23-mm prosthesis has been considered appropriate for an aortic annulus size of 18 to 22 mm and the 26-mm device for an aortic annulus size of 21 to 26 mm, with the larger prosthesis being used where possible. Because the PHV is sized according to annulus dimension measured by TEE, the impact of any mismatch in the 2 measurements is likely to be minimal. No procedure has been cancelled on the basis of an oversize TEE annular dimension, and no devices became unstable or were displaced because of excess annular dimension. If the TTE measurement only had been used to size the PHV, we believe that the TEE measurement may have modified the TTE estimate sufficiently to lead to a change in PHV size in 5 patients. For patients with borderline vascular access, accurate annular sizing by TEE has given the operator confidence to use the smaller (23 mm) PHV when annulus has been measured in the 22- to 23-mm range by TTE.

Echocardiography will perform an even more important function in PHV sizing when manufacturers deliver a wider range of more specialized devices of varying dimensions.

TEE and procedural outcomes. Although TEE is now seen as an integral adjunct to PHV deployment, limitations inherent in the design of our study mean that we are unable to determine conclusively that TEE has improved procedural outcomes. Although encouraging, the nonsignificant trend toward improved outcomes in the TEE cohort might also be influenced by subtle improvements in deployment technique likely to have arisen through experience.

AR. Paravalvular AR, initially anticipated to be a major limitation, does not now seem likely to limit the application of this technique AR is most likely to occur if the fabric cuff is not approximated to the plane of the annulus. Even with correct device positioning, AR may occur at sites adjacent to areas of leaflet compression where accumulated nodular calcium and leaflet tissue mean that a snug seal cannot be obtained. Aortic regurgitation tends to be graded higher by TEE than by early post-procedural TTE. This may be due to interpretative differences between the 2 imaging techniques, restitution of leaflet shape after initial balloon deformation, or thrombosis in the zone between the crushed aortic valve leaflet and stent.

The difficulties in accurately assessing paravalvular AR by standard echocardiographic methods remain an important limitation of this study. It is important to note that published guidelines relate to native valve regurgitation (5), and for a variety of reasons the traditional echocardiographic approaches to quantitating paravalvular AR may be limited. We have observed in many instances that the vena contracta of the paravalvular AR jet is either crescentic in shape or consists of multiple small jets. Therefore it seems unlikely that standard measures of jet height and

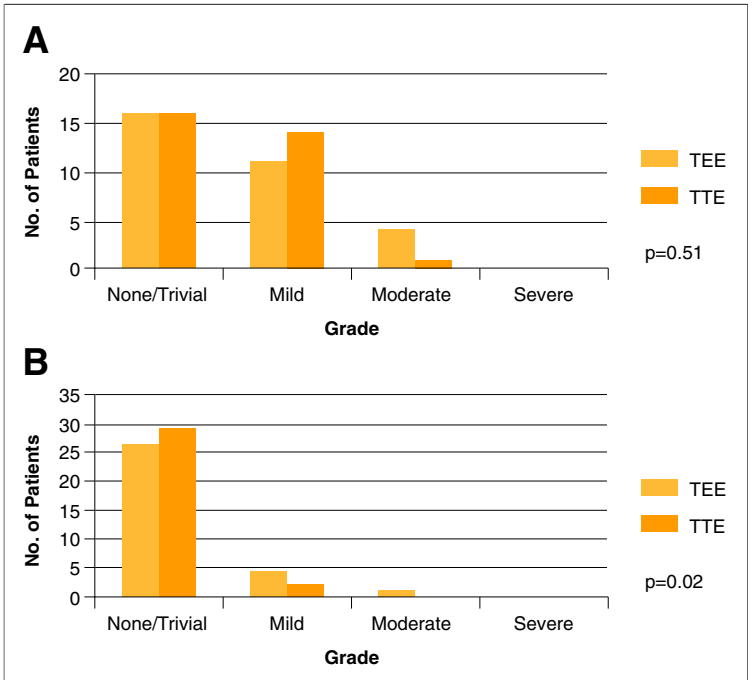

Figure 8. A Comparison of Valvular and Paravalvular AR as Graded by TEE and TTE After Successful TEE-Guided PHV Implantation (n = 31)

The grade of paravalvular and valvular AR tended to be higher in the early TEE assessment, although this was only significant for valvular AR ($p = 0.02$). **(A)** A comparison of paravalvular AR assessed by early TEE and TTE. **(B)** A comparison of valvular AR assessed by TEE and TTE. Less valvular AR was observed at post-implantation TTE assessment. Transesophageal echocardiography AR grade is the final grade at the end of the procedure. Transthoracic echocardiography refers to the grade of AR on the pre-discharge TTE. Abbreviations as in Figures 1 and 4.

dimension and vena contracta width will accurately assess the AR in that they are constrained by inherent geometrical assumptions. Similarly convergence methods for quantitating AR severity assume a circular regurgitant orifice. An ideal solution would be to volumetrically determine regurgitant fraction and regurgitant volume; however, this approach is limited by the technically difficult nature of many of our studies and the presence of significant mitral regurgitation in others. Pressure half-time determination of AR severity is limited in that it reflects aortic and ventricular compliance as well as orifice area, and like the other techniques, is unvalidated in this setting.

The incidence of minor degrees of paravalvular AR after conventional surgical aortic valve replacement is variable but may be as high as 48% (7,8). The clinical significance of small paravalvular AR jets is likely to be benign and the regurgitation nonprogressive in the majority of patients (8). Based on the surgical experience, therefore, it seems unlikely that the minor degrees of early AR that we have seen after PHV implantation will translate into clinically important long-term effects, assuming device stability is maintained.

Left ventricular ejection fraction and MR. Early improvements in left ventricular ejection fraction and mitral regurgitation following PHV implantation (Table 1) have been reported and are more extensively discussed elsewhere (9).

CONCLUSIONS

The feasibility and relative safety of PHV implantation has now been demonstrated, as having important and potentially clinically significant improvements in aortic valve hemodynamics. As the technical aspects and clinical understanding of this technique continue to evolve, echocardiography will have a crucial role in the future development of the percutaneous treatment of aortic valve disease.

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APPENDIX

For accompanying videos, please see the online version of this article.