



Original Article

Intraoperative three-dimensional transesophageal echocardiography for assessing the defect geometries of mitral prosthetic paravalvular leak during transcatheter closure

Jeng Wei, Wei-Hsian Yin, Yung-Tsai Lee, Ming C. Hsiung, Shen-Kou Tsai*, Yi Cheng Chuang, Ching-Huei Ou, Yi-Pen Chou

Heart Center, Cheng-Hsin General Hospital, Taipei, Taiwan, ROC

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Abstract

Background: Paravalvular leaks (PVLs) are a common complication of prosthetic valve replacement. Use of the transcatheter intervention technique is a suitable alternative in high-risk patients who may not tolerate repeat surgery. Common reasons for failure of this demanding intervention include poor imaging quality and unsuitable anatomy. The purpose of this study was to assess the usefulness and the incremental value of real-time three-dimensional (RT 3D) transesophageal echocardiography (TEE) over two-dimensional (2D) TEE findings in the evaluation of the geometry and track of mitral PVLs during transcatheter closure.

Methods: Five patients with six mitral PVLs at high risk for repeat surgery underwent transcatheter leak closure. Intraoperative RT 3DTEE was used to assess the location, shape, number, and size of the defects. Transapical approaches were used in all cases with fluoroscopic and RT 3D TEE guidance of the wire and catheter, device positioning, and assessment of residual leak after the procedure.

Results: In all of the cases, defects with irregular crescent shapes and distorted tracks were clearly delineated by RT 3D TEE. This was compared to those results obtained through 2D TEE, which was unable to characterize the defects. Three cases showed small leaks, which were completely occluded with a patent ductus arteriosus (PDA) device in two cases, and a muscular ventricular septal defect (mVSD) occluder combined with coil devices in one case. One case involved a large leak and early device embolization of the muscular VSD occluder, which was removed surgically, and demonstrated a crescent-shaped defect. One patient had two re-leaks 2 months subsequent to the procedure due to two new extended leaks at the tails of the crescent-shaped defect.

Conclusion: RT 3D TEE can clearly delineate the geometries of defects in their entirety, including shape, size, and location of the defect and track canal. It would also appear that RT 3D TEE is superior to 2D TEE in the process of guiding the wire through the difficult canal anatomy, facilitating the overall procedure. The small mitral PVLs can be completely occluded, but subsequent complications occurred with large defect closures because of embolization or re-leak. Therefore, transcatheter closure of PVLs seems to be an attractive alternative for these patients, but newer occluder designs that better conform to leak geometry will be required to improve outcomes.

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Keywords: mitral prosthetic paravalvular leak; occluder; real-time 3D TEE; transapical approach; transcatheter closure technique

1. Introduction

Prosthetic valves at least several hundred thousand in number (mechanic and bioprosthetic) are implanted each year. However, paravalvular leaks (PVLs) may be detected in up to 5% of patients by echocardiography.^{1–5} PVLs are a common complication of prosthetic valve replacement and occur most

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* Corresponding author. Dr. Shen-Kou Tsai, Cheng-Hsin General Hospital, 45, Cheng Hsin Street, Beitou, Taipei 112, Taiwan, ROC.

E-mail address: ch9198@chgh.org.tw (S.-K. Tsai).

commonly in patients with mitral prostheses. The majority of leaks are usually asymptomatic, but some may cause heart failure, arrhythmias, or hemolysis. Surgical reoperation carries an increased challenge of PVLs and is associated with considerable mortality and morbidity.^{6,7} Recently, several small studies showed that percutaneous closure of PVLs is a feasible option for patients who are not candidates for surgery.^{6,7}

However, the regurgitant jet produced by mitral PVLs has a complex geometry between the prosthetic ring and the surrounding native tissue. The shape and track of the defect viewed by conventional two-dimensional transesophageal echocardiography (2D TEE) imaging alone can be misleading, resulting in procedural difficulties. However, the entire geometry of the mitral valve (MV) can be delineated by real-time three-dimensional transesophageal echocardiography (RT 3D TEE).^{8–11} Therefore, we attempted to determine whether intraoperative 3D TEE provided the incremental value over 2D TEE for the assessment of defect geometry including the shape, size, track, and location of mitral PVLs.

2. Methods

After approval by the ethics committee of our hospital (CHGH-IRB-103E-01) we reviewed patients who underwent attempted PVL closure conducted from May 2012 to March 2013. Five patients with severe symptomatic mitral PVLs and following poor results in palliative medical therapy at high risk for repeat surgery underwent transcatheter leak closure. All procedures were performed under general anesthesia in a hybrid surgical room. In all cases, transapical approaches were used under fluoroscopic and RT 3D TEE guidance.

2.1. TEE examination

Intraoperative 2D TEE and RT 3D TEE were performed with a 5.5 MHz new matrix array X7-2t transducer and a commercially available Philips iE33 ultrasound system (Philips Medical System, Andover, MA, USA) after induction of anesthesia and endotracheal intubation. RT 3D TEE was performed at the end of a comprehensive 2D TEE examination. RT 3D TEE can delineate the surgical view of the online MV anatomy. Moreover, the mitral prosthesis images can be presented in the surgical view, in which the aortic valve is rotated and positioned at 12 o'clock, making the left atrial appendage at the 9 o'clock position. This allows for defining of the position of a dehisced segment relative to this imaginary clock (Fig. 1). RT 3D TEE was not only able to assess the shape, size, track, and location of mitral PVLs, but it was also able to provide guidance of the wire and catheter, facilitate device positioning, and assess residual leak after the procedure. Using 3D zoom modality, the entire mitral prosthesis can be seen “en face” and the PVL orifices identified. The full volume modality allows the demonstration of Doppler color flow through the leak site. TEE is also crucial for detection of the presence of thrombi, pericardial fluid, artifacts, and acoustic shadows during the procedure.

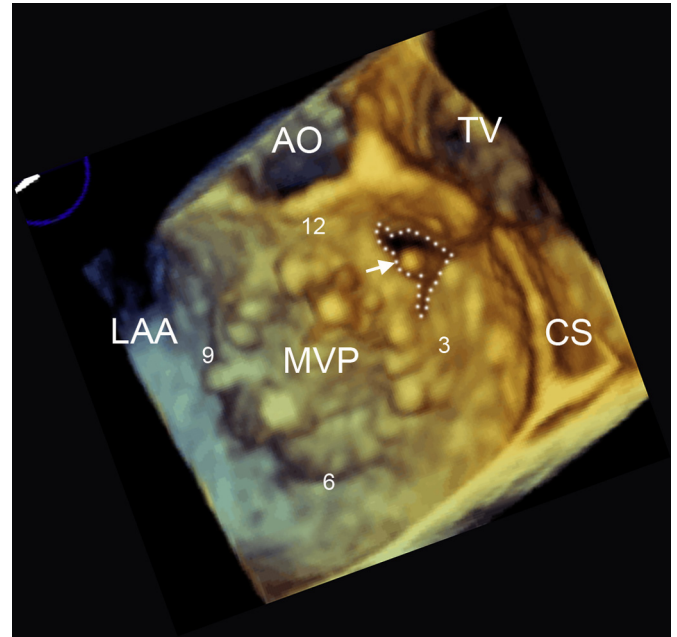


Fig. 1. Three-dimensional transesophageal echocardiography reconstructions of an imaginary clock viewed from the left atrium with a mitral paravalvular leak at the 2 o'clock position (broken line) with an irregular crescent shape and a catheter (arrow) passed through. AO = aorta; CS = coronary sinus; LAA = left atrial appendage; TV = tricuspid valve.

2.2. Device selection

The device size was chosen to be 2 mm larger than the minimal diameter of the defect. An Amplatzer coil, as well as duct and muscular ventricular septal defect (VSD) occluders (AGA Medical Corporation, North Plymouth, MN, USA), were used for deployment.

3. Results

The devices were successfully and uneventfully implanted in those five cases with six PVLs without any complication of pericardial effusion, thrombosis formation, or neurologic sequence. In this study, RT 3D TEE clearly delineated the localization, shape, and size of the defect and the track of the canal, which can be very difficult to engage and cross with the guidewire (Fig. 1). In our cases, the majority position of mitral PVLs occurred between 12 o'clock and 3 o'clock (anterior more than posterior and septal more than lateral). The incidence of mitral PVLs is no different between mechanical and bioprosthetic valves, but occurs more often in patients with combined mitral and aortic replacements (3 cases). The results of these data are shown in Table 1. Two cases with small leaks (<6 mm) were completely occluded by a duct occluder (Fig. 2). One patient with a residual leak underwent muscular VSD occluder implant and an additional coil device was implanted to achieve complete closure (Fig. 3). One case had an early embolization of the plug (12-mm VSD muscular occluder) after implantation, which was successfully removed surgically. Intraoperative findings revealed that the defect had an irregular crescent shape (Figs. 1 and 4). In one case, two

Table 1
Procedure and results of paravalvular leak closures.

Age	Sex	Valve type (prosthesis)	Size (mm)	Location ^a (o'clock)	Device (mm)	Outcome
70	M	MVR (M)	12	3	mVSD (12)	Early dislodged
83	M	MVR + AVR (B)	4	3	PDA (6 × 4)	Complete closure
72	F	MVR (M)	7	11	mVSD (8) + coil (3)	Complete closure
77	F	MVR + AVR (B)	3.8	12	PDA (6 × 4)	Complete closure
59	M	MVR + AVR (M)	8 & 10	2 & 8	mVSD (8 & 10)	Repeat surgery (2 mo later)

AVR = aortic valve replacement; B = bioprosthesis; M = mechanical prosthesis; MVR = mechanical valve replacement; mVSD = muscular ventricular septal defect; PDA = patent ductus arteriosus.

^a Surgical time clock.

leaks were occluded with an 8-mm and 10-mm muscular VSD occluder at the 3 o'clock and 10 o'clock positions, respectively. Unfortunately, re-leak and severe hematuria occurred 2 months after the closure. Repeat surgery was performed, which demonstrated that the two occluders were seated appropriately at the leak site and proved difficult to remove by forceps during surgery. Additionally, new extended residual leaks were present around the occluders at both ends of the crescent defect (Fig. 5). Thereafter, the patient died 1 week after surgery because of persisted leak, hemolysis, and heart failure. Follow-up of patients was conducted at a median of 120 days.

4. Discussion

PVLs are most commonly related to disruption of the sewing ring sutures precipitated by infectious endocarditis, which may be accompanied by abscess formation or significant calcification and fibrotic scar of the annulus. Transcatheter closure of PVLs using an occluder device was first described in 1992.^{1–5} Since that time, this technique has slowly evolved with various technical improvements, and now is a suitable alternative to repeat surgery in patients at high surgical risk with appropriate defect geometries. The transapical approach was chosen for our cases because it is more suitable for PVL closure. The transapical approach can be an alternative in cases of a failed attempt using the percutaneous route or in cases with significant difficulties in the passage through the leak canal. Crossing the leak with the guide wire may be a challenge in some patients, especially those with leak canals that are serpiginous. The utilization of 3D TEE is

highly recommended to guide the procedure because it easily depicts spatial orientation at any point during the intervention, particularly facilitating the wiring of the defect as well as confirming adequate device deployment.

Our cases demonstrated that PVLs most frequently occurred at the antero-septal aspect of the MV, especially in patients with combined double-valve replacements. There are two reasons that may account for this result. First, the antero-septal aspect of the MV is a narrow, fibrous tissue band that connects the aortic and mitral valve, also known as the aortomitral curtain,¹² which can increase the technical difficulty of the approach to the surgical suture. In addition, patients with aortic root infection or abscess formation are at a high risk of developing PVLs. In our case series, such a leak was not related to the prosthesis material, either mechanical or biotissue. Our cases suggested that the shape and size of a PVL might be a paramount factor in the success of the procedure, with smaller leaks (<6 mm) showing a higher success rate for complete closure. The 3D images demonstrated that a small leak was in an irregular tubular linear shape with a distorted fistula tract and was easier to completely close using a duct occluder as it becomes a tapering conical shape allowing the retention disc to engage the distorted tract (Fig. 2). The closure of PVLs with small leaks using an Amplatzer duct occluder (AGA Medical Corporation) is feasible for PVL closures. Although the Amplatzer duct occluder lacks a retention rim on one side, which may compromise stability, the distorted fistula tract of the leak may deform the waist of the device to form a small retention ring on the other end and tightly engage the neck of the PVL tract.

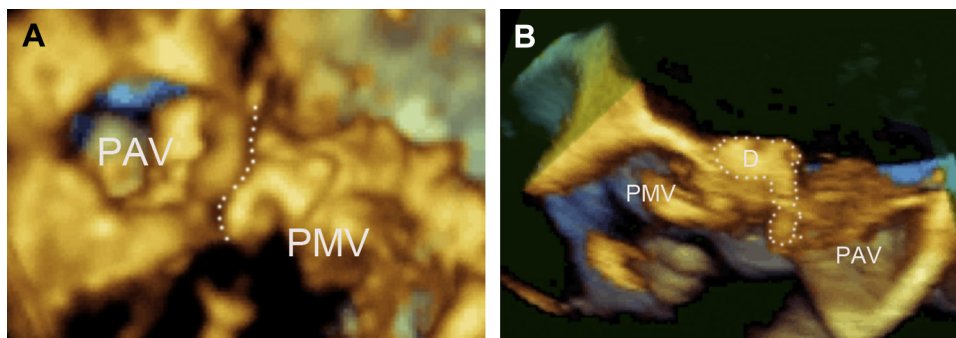


Fig. 2. (A) Three-dimensional transesophageal echocardiography reconstruction of the track of the mitral paravalvular leak with tortuous canal (broken line). (B) A patent ductus arteriosus occluder, D, with a conical shape allowing the retention disc to engage the distorted tract at the narrow site of the track. PAV = prosthetic aortic valve; PMV = prosthetic mitral valve.

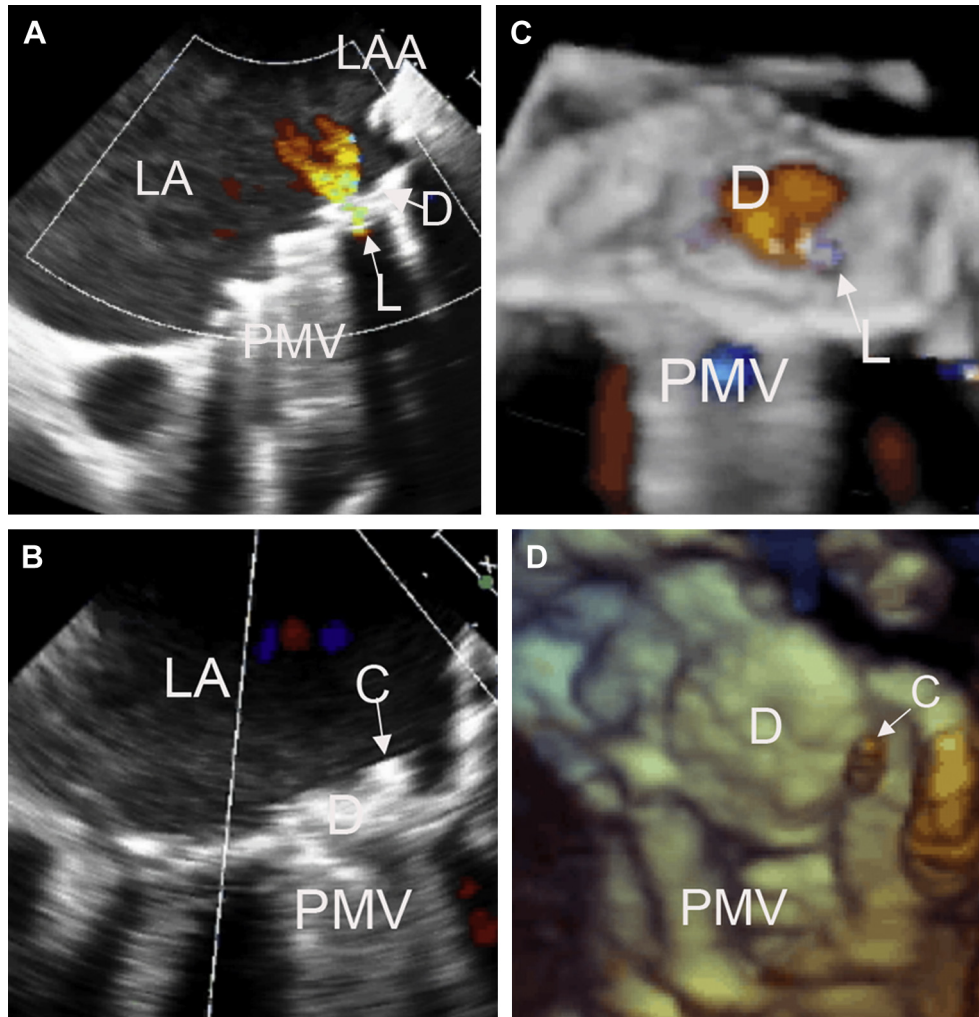


Fig. 3. (A) Two-dimensional color transesophageal echocardiography (3D TEE) showing a residual leak (L) after a muscular ventricular septal defect occluder (D in figure) implanted. (B) The residual leak was completely occluded by an additional coil device, C. (C) The corresponding 3D color TEE image (en face LA view) from image A. (D) The corresponding 3D TEE image (en face LA view) from image B. LA = left atrium; LAA = left atrial appendage; PMV = prosthetic mitral valve.

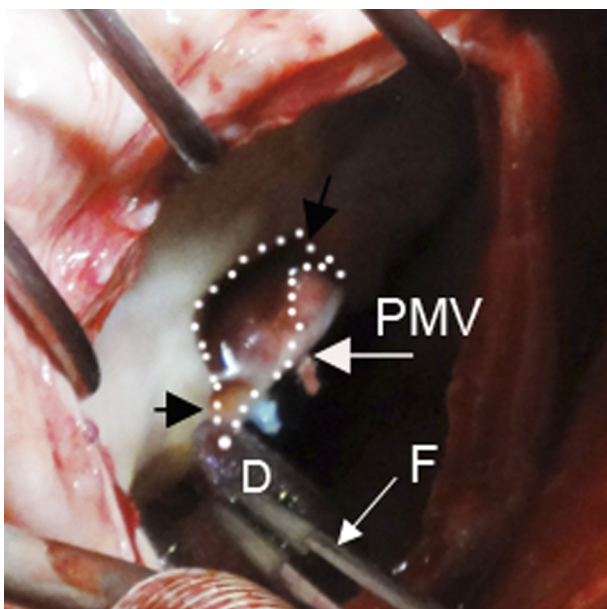


Fig. 4. An embolization of device (D) was removed by forceps (F) during surgery, demonstrating an irregular crescent shape mitral paravalvular defect. PMV = prosthetic mitral valve.

On the contrary, the larger defects of mitral PVLs located along the round border of the mitral prosthetic ring form a crescent defect or an irregular crescent shape (Figs. 2 and 3). Due to the tension of the radial forces of the round waist of the occluder inside the crescent-shaped defect, the leaks may extend into the adjacent tissue in patients with previous infections or annular calcifications, worsening the regurgitation and causing recurrent regurgitation or even embolization^{13,14} (Fig. 3) despite various devices used to close them.

Because the tract of the crescent-shaped defect can be parallel, perpendicular, or even tortuous, newer occluder designs are required to conform to the unique shape¹⁵ and track of each leak. Whereas transcatheter treatment of atrial septal defects (ASDs) and patent foramen ovale (PFO) involves closing a communication between two chambers on a similar plane, mitral PVLs are asymmetrical in structure. As such, a large retention disc of the device facilitates anchoring, but carries a higher risk of interfering with the valve itself. The Amplatzer muscular VSD occluder or duct occluder (AGA Medical Corporation) have a smaller retention disc, so these devices are favored in situations with close proximity to

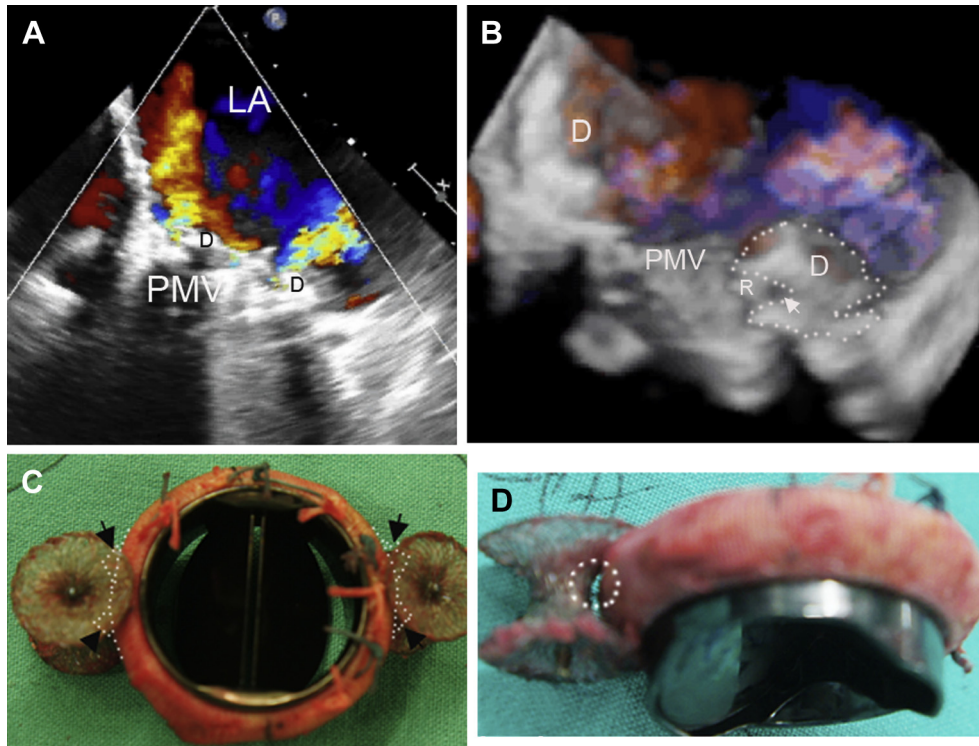


Fig. 5. (A) Two-dimensional color transesophageal echocardiography (TEE) demonstrates two leaks' jets after two muscular ventricular septal defect (VSD) occluders, D, were implanted for mitral paravalvular leaks (PVLs). (B) The corresponding three-dimensional color Doppler TEE image demonstrating location of residual leak (R, arrow) next to implanted occluder (D in figure, broken lines). Surgical model of mitral PVLs with surgical removal of prosthetic mitral valve and muscular VSD occluders. (C) Two residual leaks at two tails (white triangle line) of crescent-shaped defect fixed with round waist occluder. (D) A gap (broken circle) formation between the prosthetic ring and device. D = device; PMV = prosthetic mitral valve.

relevant surrounding structures. The recent Amplatzer Vascular Plug III¹ (AGA Medical Corporation) with an oval disc and waist may provide better features for PVL closure.

Our findings suggest that until a newer occluder is designed for the repair of larger leak defects, there is no single device that can be used to completely accomplish leak closure. One occluder, utilizing either the muscular VSD or Vascular Plug III, combined with a coil to form a crescent shape, is necessary to completely close a large leak (Fig. 4). To prevent a repeat procedure due to a high incidence of residual leak, two wires may be used to cross the leak site simultaneously in the event the first attempt fails to completely occlude the defect. The second wire serves as a backup so that if a residual leak occurs, a coil occluder can be placed without difficulty. Oversized occluders should be avoided to prevent worsening of the original leak.

In conclusion, PVL defects have more complex geometries than ASDs, which make transcatheter closure of PVLs more technically challenging compared to ASD and PFO closures, even though similar occluders are used. Therefore, the high rate of residual leak (approximately 40%) remains the main challenge with transcatheter closure of mitral PVLs. Even though the study sample was small, the initial limited results appear to suggest that this procedure currently may not be suitable for those patients with a large PVL defect, and that 3D TEE could be helpful for selecting suitable cases. However, our findings are consistent with those of Hizazi,¹⁶ indicating that although

transcatheter closure of PVLs seems to be an attractive alternative for patients at high risk for repeat surgery, newer designed occluders that better conform to leak geometry will be necessary for improved outcomes.^{17,18} With the equipment currently available, RT 3D TEE was shown to be superior to 2D TEE in both its ability to more comprehensively characterize defect geometry for case selection and to facilitate the procedure.

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