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Original Research

Intracardiac Echocardiography-Guided Percutaneous Mitral Balloon Commissurotomy: Technique and Early Experience



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ABSTRACT

Background: Percutaneous mitral balloon commissurotomy (PMBC) is the gold standard for the treatment of patients with symptomatic rheumatic mitral valve (MV) stenosis and favorable valve morphology. Intracardiac ultrasound (ICE)-guided PMBC is an attractive alternative to standard transesophageal echocardiography guidance for simplification of procedure and avoiding general anesthesia.

Methods: We conducted a retrospective analysis of all ICE-guided PMBC cases at our institution between July 2020 and November 2023. Procedural success was defined as post-PMBC MV area \geq 1.5 cm²; or an increase of \geq 0.5 cm² in MV area associated with echocardiographic mitral regurgitation (MR) that is \leq moderate post-PMBC. Six-month follow-up data were collected.

Results: We identified 11 subjects for whom ICE-guided PMBC was attempted. The mean age of the subjects was 61.7 (± 12.1) years. All, but one, were females. Out of the 11 subjects, 2 did not undergo PMBC; one had baseline severe MV regurgitation identified on ICE, and the other developed a pericardial effusion following transeptal puncture that needed an urgent pericardial window. The protocol-defined procedural success was achieved in all nine patients who underwent PMBC. Post-PMBC mean MV gradient was 4.4 (± 2.0) as compared to 11.1 (± 2.9) mmHg at baseline. At 6-month follow-up, 8 of the 9 patients had \leq New York Heart Association class II symptoms. Conclusions: ICE-guided PMBC appears to be feasible and safe. ICE-guided PMBC offers several advantages over transesophageal echocardiography guidance including improving patient comfort and eliminating the need for patient intubation and general anesthesia.

ABBREVIATIONS

GA, general anesthesia; IAS, interatrial septum; ICE, intracardiac ultrasound; LA, left atrium; MR, mitral valve regurgitation; MV, mitral valve; PMBC, percutaneous mitral balloon commissurotomy; RA, right atrium; RMS, rheumatic mitral valve stenosis; TEE, transesophageal echocardiography; TSP, transseptal puncture; TTE, transthoracic echocardiography.

Introduction

Rheumatic mitral valve stenosis (RMS) is a chronic progressive condition characterized by mitral commissural fusion and calcification leading to elevated left atrial (LA) pressure and pulmonary congestion. The incidence of RMS in developed countries has sharply declined over the past several decades. Nevertheless, RMS remains an important cause of morbidity and mortality in young adults. In the 2003 Euro Heart Survey on valvular heart disease, mitral stenosis represented 12% of total valvular diseases with RMS accounting for about 85% of these cases. Once patients with RMS develop New York Heart Association (NYHA)

class III or IV symptoms,⁴ their survival precipitously drops unless the valve is intervened upon.

Percutaneous mitral balloon commissurotomy (PMBC) is a class 1A indication for treatment of patients with symptomatic RMS if the valve anatomy is favorable and the patient has less than moderate mitral valve regurgitation (MR).⁵ Alternatively, mitral valve (MV) surgery is recommended (class 1B) for patients for whom PMBC is not feasible.⁵ PMBC is typically guided by transesophageal echocardiography (TEE). However, intracardiac ultrasound (ICE) guidance provides an alternative, less invasive option that is less resource-intensive. There is sparse data on the utility and effectiveness of ICE-guided PMBC. In this case series, we

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present our institutional experience, review technical considerations, and discuss the potential advances of this approach.

Methods

We conducted a retrospective review of our institutional cardiac catheterization laboratory database extending from July 2020 to November 2023. Quiring our database for the period prior to July 2020 was limited by a switch to a new electronic medical records system at our institution. The system was quired for the following key words: mitral valvuloplasty, mitral valvuloplasty, or mitral commissurotomy.

The charts of the patients were then reviewed by the investigators, and the baseline clinical, echocardiographic, and procedural characteristics were extracted using a standardized form. One- and 6-month follow-up data were collected from the chart, and when not available, a phone call was made to the patients.

Successful PMBC was defined as MV area $\geq 1.5~\text{cm}^2;$ or an increase of $\geq 0.5~\text{cm}^2$ in MV area associated with echocardiographic MR that is \leq moderate post-PMBC. Trans-MV gradient was obtained using pulsed wave Doppler using the ICE catheter. Procedure time was calculated as the time between needle puncture for access and removal of the last sheath. Continuous data were summarized as mean \pm standard deviation, whereas categorical data were summarized using percentages. The study was approved by our institutional review board.

Protocol and Technique

All cases were evaluated by an interventional cardiologist and a cardiac surgeon as part of a heart team approach. Preprocedural transthoracic echocardiography (TTE) was obtained on all patients to assess the severity of RMS, Wilkin's score, and MR if present. Special attention was given to the degree and asymmetry of commissural calcification, as these two factors are strongly associated with poor outcomes.⁵

Access

US-guided venous right femoral vein access is our default. The first access point is typically used for the ICE catheter (8 Fr sheath for the AcuNav and 10 Fr for the VeriSight Pro), with placement of a long sheath to minimize interaction between the ICE catheters and PMBC catheter system. A second access is obtained in the ipsilateral common femoral vein utilizing the 12 Fr long sheath for the INOUE-BALLOON PMBC system. A 5 Fr arterial access is obtained on the contralateral femoral artery, and a 5 Fr pigtail catheter is used to cross to the left ventricle (LV). Once access is obtained, the patient is heparinized to achieve an anticoagulation time of $\geq \! 250$ seconds.

ICE-Guided LA, MV Evaluation, and Transseptal Puncture

Prior to commencing transseptal puncture (TSP), it is important to adequately evaluate the LA and LA appendage, as the presence of a LA thrombus is a contraindication for TSP. With the ICE catheter positioned in the mid-right atrium (RA), the RA and right ventricle "home position" are visualized. From the home position, the catheter is clocked until the LA comes into view. The catheter is then retroflexed to visualize the "roof" of the LA and then slightly anteflexed to see the LA appendage, which appears as an outpouching of the LA (Figure 1). The LA appendage should be evaluated in multiple planes to exclude the presence of a thrombus. Next, the MV is evaluated by retracting the catheter 1 or 2 cm to the MV level and turning on the color function to assess for MR. Moderate MR or more is a contraindication for PMBC.

The interatrial septum (IAS) can be visualized by clocking the catheter and retroflexing from the home position (Figure 2). The recommended location to traverse the IAS is Fosa Ovalis (FO). Before crossing the IAS, the location of the tent made by the transeptal needle or crossing system should be evaluated in two orthogonal planes to assess the anterior



Figure 1. Intracardiac ultrasound image of the left atrium. The red arrow points to the left atrial appendage.

Abbreviations: LA, left atrium; RA, right atrium.

posterior dimension (aortic valve short axis) and the superior inferior dimension (bicaval view). We recommend crossing the FO in the midpoint of these two planes to help with an anterior trajectory toward the MV.

Crossing of the ICE Catheter Into the Left Atrium

Following TSP, there are two different approaches for imaging the Inoue balloon during commissurotomy and obtaining the trans-MV gradients. The first is imaging from the RA using the ICE catheter. In this

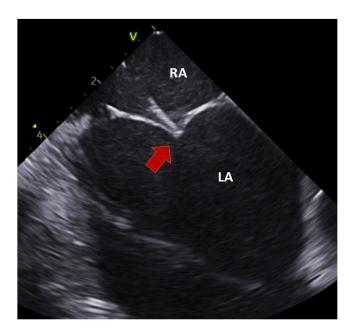


Figure 2. Intracardiac ultrasound image of the left atrium. The red arrow points to the Brockenbrough needle tenting the interatrial septum. Abbreviations: LA, left atrium; RA, right atrium.

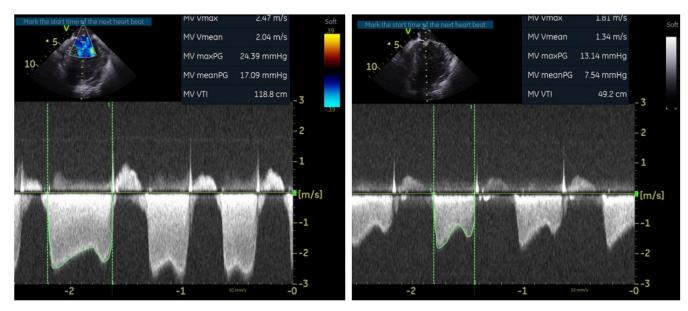


Figure 3. Pulsed wave Doppler images of the mitral valve demonstrating mitral valve gradient before and after percutaneous mitral balloon commissurotomy. Abbreviation: MV, mitral valve; PG, pressure gradient; VTI, velocity time interval.

approach, TTE is required to obtain trans-MV gradients post-PMBC, typically using the apical 4 chamber view. In the second approach, the ICE catheter is advanced across the IAS into the LA and used to image the MV to obtain trans-MV gradients. Intraoperative TTE is not needed with this approach.

If the second approach is preferred by the operator, after TSP, the IAS is "flossed" several times using the 14 Fr dilator that is advanced, then retraced over a stiff wire that is traversing the IAS and parked in the left upper pulmonary vein. For crossing the ICE catheter from the RA to the LA, the catheter is buddied to (superimposed on) the guide wire in the inferior vena cava under fluoroscopy in the left anterio oblique position, then advanced 2 cm before moving the image intensifier to the right anterior oblique position to ensure the wire and the catheter remain buddied (Video 1). Adjustments are made to the position of the catheter, and the processes are repeated several times as the catheter is advanced 2 cm at a time from the RA across the IAS to the LA. The adjustments are posterior and anterior flexion in the left anterio oblique projection and clock-counter clock rotation in the right anterior oblique projection to remain in a "buddy position" to the guide wire. The ICE catheter is then anteflexed to look down at the MV (Figure 3). Baseline MV gradient and severity of MR are assessed prior to PMBC.

PMBC

The Inoue system is our default choice for PMBC. The Inoue system was prepared outside the body, and the included valvuloplasty balloon size is determined based on patient's height and weight as per manufacturer's instructions. The inflated balloon size is then confirmed using the provided ruler.

The Inoue catheter is advanced over the provided 0.025" wire across the IAS to the LA parallel to the ICE catheter. The balloon stretching tube and guide wire are then removed, and the distal portion of the Inoue balloon is partially inflated using diluted contrast. The stylet is then introduced into the Inoue catheter in an in-and-out motion to help direct the balloon to the LV.

Once the distal portion of the balloon is visualized to be across the MV annulus, more volume is added to the balloon, and the operator tugs on the balloon to ensure it is well seated under the MV. Additional volume is then added to inflate the atrial portion of the balloon until it resembles an hourglass. This centers the balloon on the valve and prevents migration. The final 2 to 3 mL of volume added forces further

expansion of the balloon at its waist at the level of the commissures, to complete the valvuloplasty (Figure 4, Video 2 and 3). The balloon is then quickly deflated to allow forward cardiac flow through the MV and assess results.

Post-PMBC MV gradient and severity of MR are assessed. If the reduction in MV gradient is not satisfactory and the MR is not more than moderate, repeat PMBC can be attempted using the same technique. Prior to completion, MV gradient and severity of MR using ICE or TTE are assessed. Additionally, an invasive trans-MV gradient utilizing the transduced pressure from the pig tail catheter in the LV and the Inoue catheter in the LA is obtained.

Results

Between July 2020 and November 2023, 11 consecutive cases of PMBC were identified. All 11 cases were performed by one of two operators under ICE guidance. Table 1 describes the baseline clinical characteristics of these patients. The mean age of the patients was 61.7 (± 12.1) years. All subjects, but one, were female, and all subjects had NYHA class III or IV symptoms prior to the PMBC. Rheumatic heart disease was the etiology for MV stenosis in all patients. Four of the 11 subjects had a history of atrial fibrillation.

Out of the 11 cases, two were aborted during the procedure, the first after ICE identified severe MR prior to PMBC. The MR was missed on the preprocedural TTE. The second case was aborted after a large pericardial effusion developed following TSP. In 10 out of the 11 cases, we used the ACUSON AcuNav 2D ICE catheter. The last case in the series utilized the VeriSight Pro 3D ICE catheter.

At baseline assessment, mean MV area was $1.1~(\pm 0.3)~\text{cm}^2$, and the mean MV gradient was $11.1~(\pm 2.9)~\text{mmHg}$. MR was trivial or mild in 4 cases and mild to moderate in 5 cases. Mean right ventricular systolic pressure was $52.1~(\pm 20.7)~\text{mmHg}$. The ICE catheter crossed to the LA to obtain post-PBMC trans-MV gradients in 4 out of the 9 cases, while in the other 5 cases we did not cross with the ICE catheter into the LA, and the trans-MV gradient was obtained using TTE.

Procedural results are described in Table 2. In the 9 cases who underwent PMBC, post-PMBC mean MV area was $2.0~(\pm 0.4)~{\rm cm}^2$, and the mean MV gradient was $4.4~(\pm 2.0)$. Post-PMBC MR was mild-moderate in 5 patients and mild in 4 cases. Protocol-defined procedural success was achieved in all patients who underwent PMBC. The mean procedural time was $104~(\pm 24.6)$ minutes. The mean fluoroscopy time was 22.2

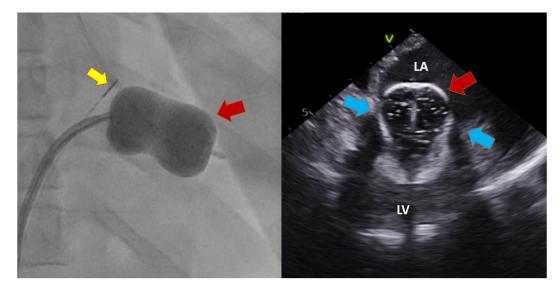


Figure 4. Fluoroscopic and intracardiac ultrasound images demonstrating the Inoue balloon inflated in in the mitral valve during percutaneous mitral balloon commissurotomy. Red arrows points to the Inoue balloon inflated in the mitral valve. Yellow arrow points to the intracardiac ultrasound catheter. Blue arrows point to the mitral valve plane.

Abbreviations: LA, left atrium; LV, left ventricle.

 (± 7.5) minutes. One of the nine patients needed percutaneous pericardiocentesis post-PMBC.

All patients were discharged from the hospital within 24 hours. On 6-month follow-up, all patients, except for one, were alive with NYHA class I or II symptoms. That patient did not get relief from her symptoms after PMBC and underwent surgical MV replacement 2 months later.

Discussion

ICE's role in invasive and structural procedures has been steadily expanding over the past decade. 6 ICE provides clear and reliable imaging of the IAS and MV. Newer generation of 3D ICE offers several advantages over 2D ICE including biplane imaging and digital steering, which allows changing the imaging plane without moving the catheter.

Our case series demonstrates that ICE-guided PMBC is feasible and safe. Protocol-defined procedural success was achieved in all 9 patients who underwent ICE-guided PMBC. One patient developed a small pericardial effusion after PMBC, which was successfully managed with percutaneous pericardiocentesis, and the patient was discharged the next day. Another patient developed a large pericardial effusion secondary to inadvertent needle migration during TSP with the needle crossing the IAS outside the Fosa Ovalis. In our judgment, this adverse event was not related to the quality of the ICE imaging. That patient was sent for urgent pericardial window and underwent surgical MV replacement at the time.

As compared to the TEE-guided PMBC, ICE offers several advantages. First, ICE eliminates the need for general anesthesia (GA) along with the risks associated with induction. Patients with advanced RMS can have

severe pulmonary hypertension and right ventricular dysfunction,⁵ and induction of GA in these patients can lead to hemodynamic instability. Second, ICE eliminates the need for endotracheal intubation, which is typically required during TEE-guided procedures. Third, in our experience, ICE is associated with improved patient comfort, which facilitates postprocedural recovery and early discharge. Finally, in ICE-guided cases, the need for an echocardiographer and anesthesiologist is eliminated, which saves on resource utilization. A comparison of the three available imaging modalities used in aiding PMBC are shown in Table 3. The use of ICE guidance for PMBC has been previously described in 2021 by Green et al. and Ahmari et al. in 2012. In both series, 19 and 17 consecutive patients with severe RMS, respectively, underwent ICE-guided PMBC with excellent results and safety profile. As compared to our case series, the operators in the two series did not cross the ICE catheter from the RA to the LA in any of their cases. In our experience, imaging the MV from the LA provides better spatial resolution as compared to imaging from the RA. More importantly, it offers excellent alignment of the Doppler signal for assessment of post-PMBC MV gradient, while eliminating the need for TTE, which otherwise would have been required to accurately assess immediate post-PMBC MV gradients in the catheterization laboratory. MV gradients obtained by the ICE catheters were reproducible in our series when compared to TTE obtained gradients obtained prior to patient discharge.

There are several limitations of ICE-guided PMBC. First, the operator must be facile with operating the ICE catheter and comfortable interpreting the acquired images. Second, there is a learning curve associated with the use of this technology and crossing the ICE catheter from the RA to the LA

Table 1
Basline patient characteristics

Patient entracted								
	Age	Sex	NYHA class	History of Afib	Etiology	Prior PMBC	Patient status	
Case 1	44	Male	3	Yes	Rheumatic	No	Outpatient	
Case 2	71	Female	3	No	Rheumatic	No	Outpatient	
Case 3	69	Female	3	Yes	Rheumatic	No	Outpatient	
Case 4	77	Female	3	Yes	Rheumatic	No	Inpatient	
Case 5	62	Female	3	No	Rheumatic	No	Outpatient	
Case 6	77	Female	3	No	Rheumatic	No	Outpatient	
Case 7	71	Female	3	No	Rheumatic	No	Outpatient	
Case 8	57	Female	3	No	Rheumatic	No	Inpatient	
Case 9	45	Female	4	No	Rheumatic	No	Inpatient	
Case 10	50	Female	3	Yes	Rheumatic	Yes	Outpatient	
Case 11	56	Female	3	No	Rheumatic	No	Outpatient	

Procedural saccess Yes Yes Yes NA Procedural adverse Abbreviations: ICE, intracardiac ultrasound; LA, left atrium; MR, mitral regurgitation; MV, mitral valve; NA, not applicable; PMBC, percutaneous mitral balloon commissurotomy; RA, right atrium. Fluoroscopy (min) 12.9 22.1 20 NA NA Procedure ime (min) 1:03 1:08 1:00 NA NA Post-PMBC Mildnoderate
Mildnoderate
Mildmoderate
Mildmoderate
Mildmoderate
Mild-Mild MR gradient (mmHg) Post-PMBC MV 5.0 7.5 NA NA Post-PMBC MV area (cm^2) 2.7 1.9 1.6 NA NA ICE catheter location during PMBC ΓĄ F Type of ICE AcuNav AcuNav AcuNav AcuNav AcuNav AcuNa Pre-PMBC noderate oderate Mild Mild-Mild-Mild-Mild gradient (mmHg) Pre-PMBC MV 14.0 12.0 17.1 11.0 5.0 10.5 9.0 Pre-PMBC MV Procedural characteristics area (cm²) 1.2 9 0 1.0 1.2 0.6 Case 10 Case 9 Case 8 Case 1 Case 4 Case 7

Table 3
Comparison of ultrasound modalities used to assist PMBC

	TTE	TEE	ICE
Aid TSP	-	+	+
Quality of MV imaging	+	++	++
Assessment of MV gradient	+	+	+ (after crossing to
			the left atrium)
3D multiplane reconstruction	-	+ (3D probes only)	+ (3D catheters only)
Need for deep sedation or GA	-	+	-
Ease of use	++	++	+
Patient convenience	++	-	+
Cost	-	+	++

Abbreviations: 3D, 3-dimensional; GA, general anesthesia; ICE, intracardiac ultrasound; MV, mitral valve; PMBC, percutaneous mitral balloon commissurotomy; TEE, transesophageal echocardiography; TSP, transseptal puncture; TTE, transthoracic echocardiography.

through the atrial septostomy. Third, interaction between the ICE catheter and the Inoue catheter can interfere with the reliability of the imaging. Fourth, the ICE catheters add to the cost of the procedure, though this is likely offset by eliminating the need for an echocardiographer and anesthesiologist during the procedure, as well as a shorter procedure and recovery time.

Conclusions

ICE-guided PMBC offers several advantages including patient comfort and eliminating the need for patient intubation and GA, which reduces utilization of hospital resources. There is a learning curve associated with the use and interpretation of ICE; however, ICE-guided PMBC appears to be feasible and safe.

ORCIDs

Ethics Statement

The research reported has adhered to the relevant ethical guidelines.

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Disclosure Statement

K. Al-Azizi reports a relationship with Edwards Lifesciences Corporation, Shockwave Medical Inc, Medtronic, and Abbott that includes consulting or advisory services. Karim Al-Azizi reports a relationship with Philips North America LLC that includes board membership and consulting or advisory services. S. Potluri reports a relationship with Boston Scientific Corp, Medtronic, Abbott, Terumo Medical Corp, and Shockwave Medical Inc that includes board membership and consulting or advisory services.

The other authors had no conflicts to declare.

Supplementary Material

Supplemental data for this article can be accessed on the publisher's website

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