TORAY

DIAGNOSIS HANDBOOK

FOR PERCUTANEOUS MITRAL BALLOON VALVOTOMY

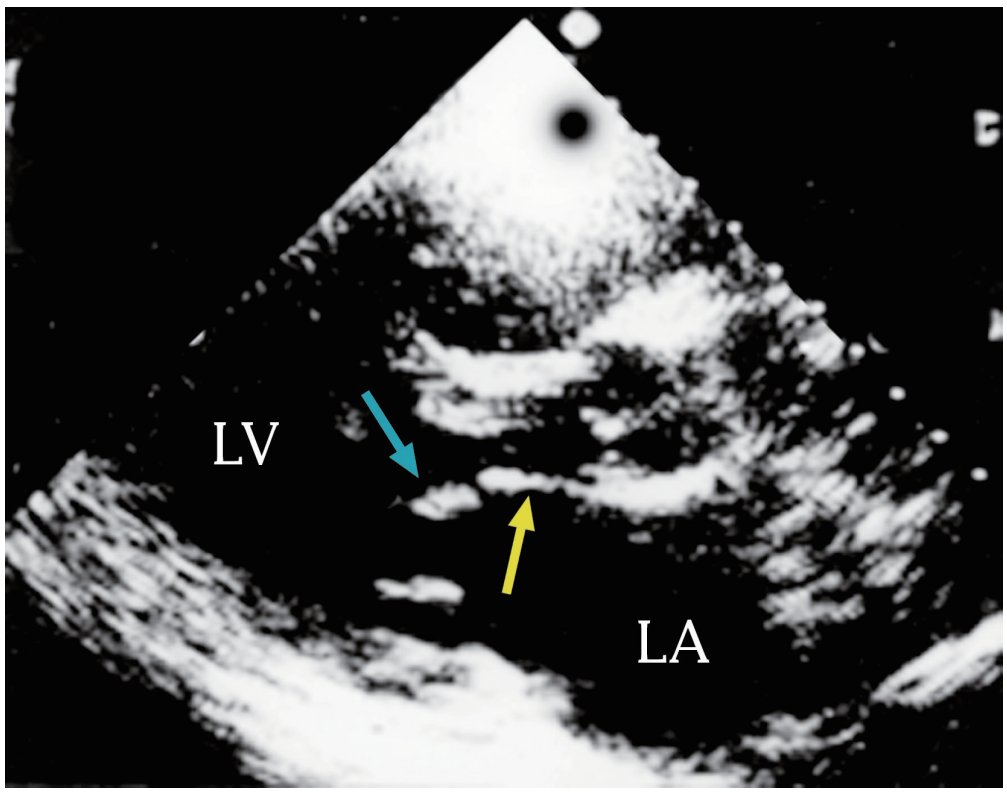
Abbreviations

CMC	Closed Mitral Commissurotomy
LA	Left Atrium
LV	Left Ventricle
MG	Mitral Gradient
MR	Mitral Regurgitation
MS	Mitral Stenosis
MV	Mitral Valve
MVA	Mitral Valve Area
MVR	Mitral Valve Replacement
NYHA	New York Heart Association
OMC	Open Mitral Commissurotomy
PMBV	Percutaneous Mitral Balloon Valvotomy

1. MITRAL VALVE STENOSIS

Pathophysiology

MITRAL STENOSIS (MS) is an obstruction to left ventricular inflow at the level of the mitral valve as a result of a structural abnormality of the mitral valve apparatus, preventing proper opening during diastolic filling of the left ventricle.



Possible Treatments

- Percutaneous Mitral Balloon Valvotomy (PMBV)

What is PMBV?

PMBV is a less invasive non-surgical intervention for dilating the stenotic mitral valve using a balloon catheter.

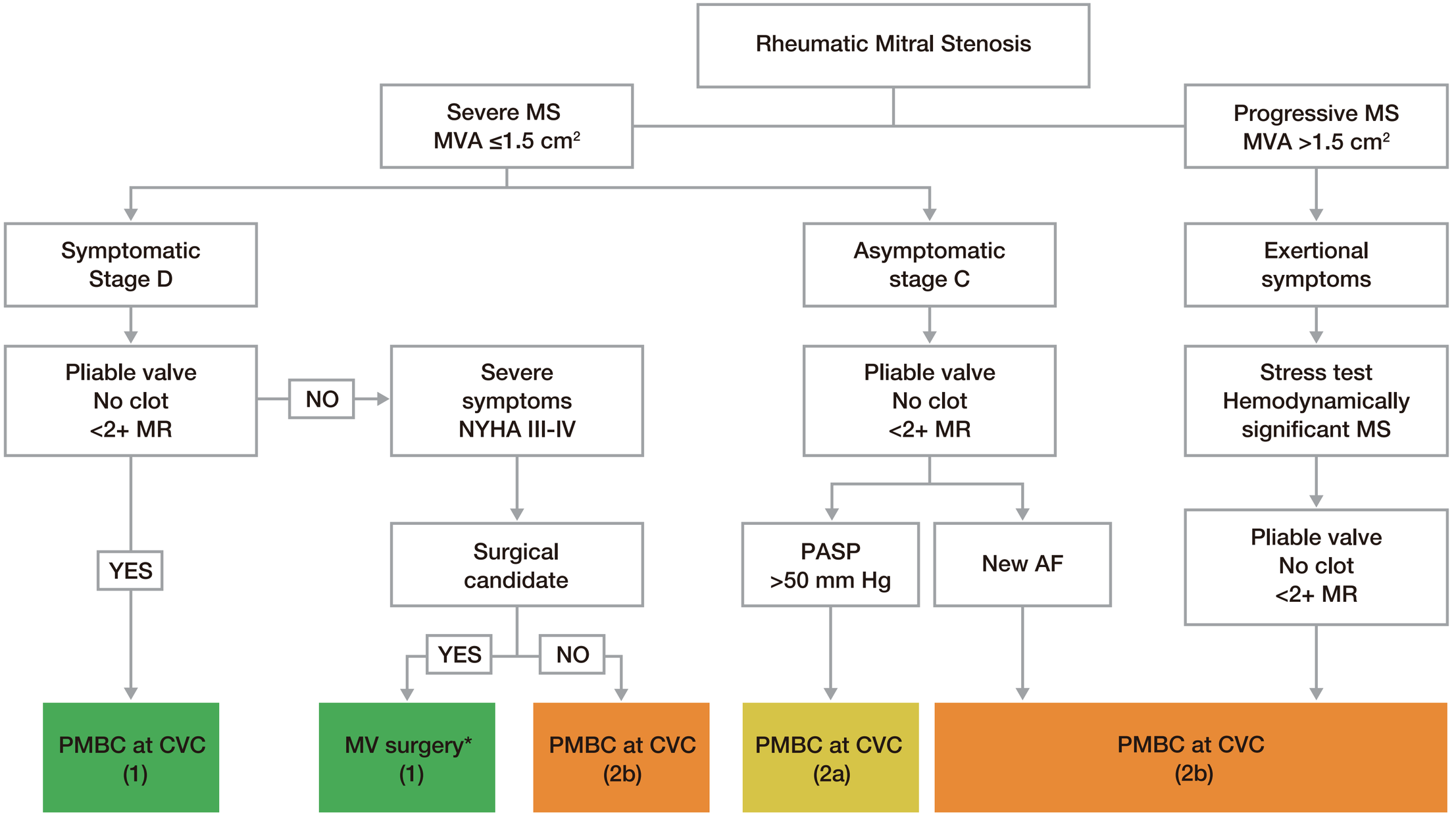
PMBV using **INOUE-BALLOON CATHETER** is termed Percutaneous Transvenous Mitral Commissurotomy, or **PTMC**.

* Inoue-Balloon Catheter is indicated for PTMC in patients with mitral stenosis.

- Mitral Valve Repair
  (Open or Closed Surgical Mitral Commissurotomy)

- Mitral Valve Replacement (MVR)

2. 1. MANAGEMENT STRATEGY FOR PATIENTS WITH MS (ACC/AHA GUIDELINES)



*Repair, commissurotomy, or valve replacement. AF indicates atrial fibrillation; CVC, Comprehensive Valve Center; MR, mitral regurgitation; MS, mitral stenosis; MV, mitral valve; MVA, mitral valve area; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; and PMBC, percutaneous mitral balloon commissurotomy.

2.2. RECOMMENDATIONS FOR PMBV

Table 1. Indications for PMBV(ACC / AHA Guidelines)

COR	LOE	Recommendations
1	A	1. In symptomatic patients (NYHA class II, III, or IV) with severe rheumatic MS (mitral value area ≤1.5 cm^2, Stage D) and favorable valve morphology with less than moderate (2+) MR* in the absence of LA thrombus, PMBC is recommended if it can be performed at a Comprehensive Valve Center.[1-12]
1	B-NR	2. In severely symptomatic patients (NYHA class III or IV) with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) who 1) are not candidates for PMBC, 2) have failed a previous PMBC, 3) require other cardiac procedures, or 4) do not have access to PMBC, mitral valve surgery (repair, commissurotomy, or valve replacement) is indicated.[6,7,13]
2a	B-NR	3. In asymptomatic patients with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage C) and favorable valve morphology with less than 2+ MR in the absence of LA thrombus who have elevated pulmonary pressures (pulmonary artery systolic pressure >50 mm Hg), PMBC is reasonable if it can be performed at a Comprehensive Valve Center.[14]
2b	C-LD	4. In asymptomatic patients with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage C) and favorable valve morphology with less than 2+/ MR* in the absence of LA thrombus who have new onset of AF, PMBC may be considered if it can be performed at a Comprehensive Valve Center.[15]
2b	C-LD	5. In symptomatic patients (NYHA class II, III, or IV) with rheumatic MS and an mitral valve area >1.5 cm^2, if there is evidence of hemodynamically significant rheumatic MS on the basis of a pulmonary artery wedge pressure >25 mmHg or a mean mitral valve gradient >15 mmHg during exercise, PMBC may be considered if it can be performed at a Comprehensive Valve Center.[16]
2b	B-NR	6. In severely symptomatic patients (NYHA class III or IV) with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) who have a suboptimal valve anatomy and who are not candidates for surgery or are at high risk for surgery, PMBC may be considered if it can be performed at a Comprehensive Valve Center.[17-19]

*2+ on a 0 to 4+ scale according to Sellar's criteria or less than moderate by Doppler echocardiography.[20]

2.3. Contraindications and/or limitations

◆ Contraindications

Contraindications for use of the Inoue-Ballon Catheter in Percutaneous Transvenous Mitral Commissurotomy (PTMC) include:

1. Mitral valve area >1.5cm^2

2. Mitral regurgitation >2+ (on a scale of 0-4)

3. Asymptomatic patients

4. Aortic regurgitation >2+ (on a scale of 0-4)

5. Bacterial endocarditis

6. Suspected formation of fresh (soft) blood thrombus in the left atrium

7. Suspected adhesion of blood thrombus on the interatial septum or valve

8. Severe subvalvular fibrosis documented by echocardiography in a patient who is an operative candidate or a good surgical risk.

9. Severe mitral valve calcification in a patient who is an operative candidate or a good surgical risk.

◆ Warnings

1. If mitral regurgitation occurs or increases significantly, the procedure must not be repeated using a larger inflation volume.

2. Patients who have severe mitral valve calcification and/or severe subvalvular fibrosis should be considered candidates for the procedure only if they are non-operative candidates or poor surgical risks.

3. LIKELIHOOD OF GOOD OUTCOME OF PMBV - Echocardiographic Score -

Wilkins echocardiographic score (echo score) is the most widely used technique for the evaluation of the morphological characteristics of the mitral valve associated with a higher likelihood of good immediate and follow-up outcome of PMBV.

The four criteria are each scored from 1 to 4, yielding a maximum total echo score of 16.

Patients with echo score ≤ 8 are more likely to have better immediate and long-term outcomes of PMBV.

Table 2. Wilkins echocardiographic score

Grade	Mobility	Subvalvular thickening	Thickening	Calcification
1	Highly mobile valve with only leaflet tips restricted	Minimal thickening just below the mitral leaflets	Leaflets near normal in thickness (4 ~ 5mm)	A single area of increased echo brightness
2	Leaflet mid and base portions have normal mobility	Thickening of chordal structures extending up to one third of the chordal length	Mid-leaflets normal, considerable thickening of margins (5 ~ 8mm)	Scattered areas of brightness confined to leaflet margins
3	Valve continues to move forward in diastole, mainly from the base	Thickening extending to the distal third of the chords	Thickening extending through the entire leaflet (5 ~ 8mm)	Brightness extending into the mid-portion of the leaflets
4	No or minimal forward movement of the leaflets in diastole	Extensive thickening and shortening of all chordal structures extending down to the papillary muscles	Considerable thickening of all leaflet tissue (> 8 ~ 10mm)	Extensive brightness throughout much of the leaflet tissue

Wilkins et al. Percutaneous Balloon Dilatation of the Mitral Valve: an analysis of echocardiographic variables related to outcome and the mechanism of dilatation. Br Heart J. 1988 Oct;60(4):299-308.

4. 1. IMMEDIATE OUTCOME AND LONG-TERM FOLLOW-UP

- Immediate outcomes of PMBV for selected patients are favorable. In a survey of 939 procedures (879 patients), over 70% of procedures were successful PMBV, which was defined as a post-PMBV MVA ≥ 1.5cm2 and post-PMBV MR < 3 by Sellers classification.
- Immediate outcome and follow-up result are significantly better for patients with echo score ≤ 8 than those with echo score > 8.

Table 3. Immediate and long-term outcome

	Total	Echo score ≤ 8	Echo score > 8
Immediate outcome of PMBV			
No. of procedures	939	634	305
Pre-PMBV MVA	0.9 ± 0.3	1.0 ± 0.3	0.8 ± 0.3
Post-PMBV MVA	1.9 ± 0.7	2.0 ± 0.6	1.6 ± 0.6
Pre-PMBV MG	14 ± 6	14 ± 6	15 ± 6
Post-PMBV MG	6 ± 3	5 ± 3	6 ± 3
PMBV success	673 (71.7%)	501 (79.0%)	172 (56.4%)
Follow-up (50 ± 45 months, mean; 4.2 ± 3.7 years)			
No. of patients	844 (96%)	575 (96%)	269 (97%)
Death	110 (13.0%)	51 (8.9%)	59 (21.9%)
Re-do PMBV	54 (6.4%)	39 (6.8%)	15 (5.8%)
MVR	234 (27.7%)	155 (26.9%)	79 (29.4%)
Event free survival	446 (52.8%)	330 (57.4%)	116 (43.1%)
NYHA I-II	417 (93.5%)	312 (95%)	105 (90%)
NYHA III-IV	29 (6.5%)	18 (5.5%)	11 (9.5%)

Palacios et al. Which Patients Benefit From Percutaneous Mitral Balloon Valvuloplasty? Prevalvuloplasty and Postvalvuloplasty Variables That Predict Long-Term Outcome. Circulation. 2002 Mar 26;105(12): 1465-71.

Remarks: Some data irrelevant to the purpose of this leaflet are excluded from the original tables.

4.2. COMPARISON BETWEEN PMBV AND SURGERY (CMC/OMC)

- There is no significant difference in acute hemodynamic results or complication rate.
- There is no significant difference in hemodynamics, clinical improvement or exercise time in early follow-up.
- Long-term follow-up studies at 3-7 years indicate more favorable hemodynamic and symptomatic results with PMBV than CMC, and equivalent to OMC.

Table 4. Comparison between PMBV, CMC and OMC

Study (year)	Mean follow up	Procedure	No. of pts	Age	Ave. score	MG		MVA		No reinter vention (%)	NYHA class I (%)
						Pre	Post	Pre	Post		
Patel (1991)	Inmediate	PMBV	23	30 ± 11	6.0	12 ± 4	4 ± 3	0.8 ± 0.3	2.1 ± 0.7*	–	91
		CMC	22	26 ± 26	6.0	12 ± 5	6 ± 4	0.7 ± 0.2	1.3 ± 0.3	–	–
Tun (1991)	7 mo	PMBV	20	27 ± 8	7.2	18 ± 4	10 ± 2	0.8 ± 0.2	1.6 ± 0.2	–	–
		CMC	20	28 ± 1	8.4	20 ± 6	12 ± 2	0.9 ± 0.4	1.7 ± 0.2	–	–
Arora (1993)	22 mo	PMBV	100	19 ± 5	–	–	–	0.8 ± 0.3	2.3 ± 0.1	–	–
		CMC	100	20 ± 6	–	–	–	0.8 ± 0.2	2.1 ± 0.4	–	–
Reyes (1994)	3 y	PMBV	30	30 ± 9	6.7	–	–	0.9 ± 0.3	2.4 ± 0.4*	–	72
		OMC	30	31 ± 9	7.0	–	–	0.9 ± 0.3	1.8 ± 0.4	–	57
Ben Farhat (1998)	7 y	PMBV	30	29 ± 12	6.0	–	–	0.9 ± 0.2	1.8 ± 0.4	90	87
		OMC	30	27 ± 9	6.0	–	–	0.9 ± 0.2	1.8 ± 0.3	93	90
		CMC	30	28 ± 10	6.0	–	–	0.9 ± 0.2	1.3 ± 0.3	50	33
Cotnifo (1999)	38 mo	PMBV	111	47 ± 14	7.6	–	–	10.0 ± 0.2	1.8 ± 0.3	88	67
	50 mo	OMC	82	49 ± 10	8.2	–	–	10.0 ± 0.2	2.3 ± 0.3	96	84

* Significant difference ($P < 0.05$) in increased MVA by PMBV compared with surgical commissurotomy.

Bonow RO, et al. ACC/AHA 2006 Guidelines for the Management of Patients With Valvular Heart Disease. J Am Coll Cardiol. 2006 Aug;48(3):e1-148.

[References]

1. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines.; Catherine M Otto, Rick A Nishimura, Robert O Bonow, Blase A Carabello, John P Erwin 3rd, Federico Gentile, Hani Jneid, Eric V Krieger, Michael Mack, Christopher McLeod, Patrick T O'Gara, Vera H Rigolin, Thoralf M Sundt 3rd, Annemarie Thompson, Christopher Toly, Circulation, Volume 143, Issue 5, 2020, Pages 2440-2492.

2. Wilkins GT, Weyman AE, Abascal VM, Block PC, Palacios IF. Percutaneous Balloon Dilatation of the Mitral Valve: an analysis of echocardiographic variables related to outcome and the mechanism of dilatation. British Heart Journal. 1988 Oct;60 (4): 299-308.

3. Palacios IF, Sanchez PL, Harrell LC, Weyman AE, Block PC. Which Patients Benefit From Percutaneous Mitral Balloon Valvuloplasty? Prevalvuloplasty and Postvalvuloplasty Variables That Predict Long-Term Outcome. Circulation. 2002 Mar 26;105 (12): 1465-71.

NOTICE

The contents of this leaflet are excerpts.
Please read through the references quoted herein.

Physicians not proficient in transseptal catheterization and PMBV procedure should not attempt PMBV.

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