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# Percutaneous Balloon Mitral Valvuloplasty

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Additional information is available at the end of the chapter

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## Abstract

Mitral stenosis (MS) is the most important long-term sequel of rheumatic fever (RF). MS is associated with deterioration of the functional status of the patients and worsens their long-term prognosis. Percutaneous balloon mitral valvuloplasty (BMV) is an effective and safe method in treating rheumatic MS when performed by an experienced operator in a carefully selected patient. A successful BMV procedure results in reducing the symptoms and improving the long-term outcome of the patients. Of the different proposed techniques, the Inoue balloon technique is the most frequently used. Appropriate patient selection using clinical and echocardiographic characteristics is of paramount importance for achieving acceptable final results. Complications are infrequent but can cause significant morbidity and even mortality. Special subgroups of patients might also benefit from BMV, including pregnant women, older patients with rigid valves, and those with mitral valve restenosis.

**Keywords:** balloon valvuloplasty, Inoue technique, mitral stenosis, rheumatic heart disease, transseptal catheterization

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## 1. Introduction

Rheumatic fever (RF) develops as the consequence of autoimmune reaction to group A beta-hemolytic streptococcal pharyngeal infection [1]. Cardiac involvement is the most important manifestation of RF and mainly presents an acute endocarditis and valvulitis. The following inflammatory and hemodynamic changes involving the cardiac valves insulted by the acute RF could result in long-standing rheumatic heart disease (RHD). The natural course of RHD depends on the severity of the initial attack and the frequency of recurrences. Unlike in developed countries, RHD is not infrequently seen in many areas of the world. Indeed, some countries have reported persistently high or even increasing incidence of RF and subsequent RHD during the recent decades [2]. All cardiac valves could be involved in patients with RHD.

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The mitral valve is almost always affected in clinically manifested patients, followed by the aortic and tricuspid valves. Mitral stenosis (MS) is the cardinal valvular lesion in RHD and is particularly amenable to transcatheter therapy when it is isolated or dominant and the anatomy is favorable. When left untreated, severe MS deteriorates the functional status of the patients and worsens their long-term outcomes [3]. Rarely, other etiologies might cause MS (i.e., connective tissue disorders, drugs, and congenital abnormalities). Today, degenerative calcified MS, failure of the bioprosthetic mitral valve, and overcorrection of mitral regurgitation (MR) are increasingly seen. Unlike rheumatic MS, these non-rheumatic mitral valve obstructions are not associated with commissural fusion and are not generally relieved by percutaneous balloon mitral valvuloplasty (BMV). When applied in correctly selected subjects and performed by experienced operators, a successful BMV procedure can improve symptoms and long-term survival of the patients and is, therefore, the method of choice in the treatment of patients with severe rheumatic MS [4, 5].

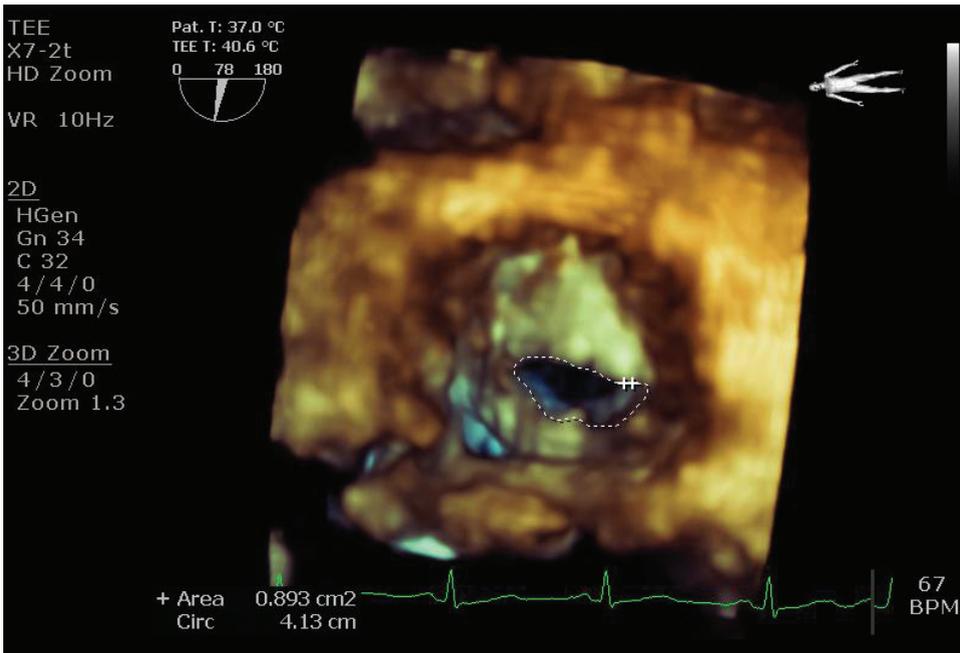
## 2. Evaluation of severity

### 2.1. Echocardiography

Echocardiography is essential in the diagnosis and quantification of the severity of MS. Transthoracic echocardiography (TTE) provides sufficient data in most patients and should be performed in patients at initial presentation, in those with changing symptoms, and in asymptomatic patients periodically (**Figure 1**). It shows the restriction of the mitral valve opening caused by commissural fusion and the so-called doming of the mitral valve, thickness and calcification of the leaflets, and chordal thickening. A mitral valve area (MVA)  $\leq 1.5$  cm<sup>2</sup> and a pressure half-time (PHT)  $\geq 150$  ms correspond to severe MS. PHT is affected by left ventricular (LV) diastolic dysfunction and the severity of mitral and aortic regurgitation, while planimetry-derived MVA is more accurate and should be used for decision-making in most patients [6]. Mitral valve resistance might be a better predictor of hemodynamic burden of MS and can be used to determine the need for BMV in borderline cases [7]. The other parameters that are evaluated include transmitral valve gradient, MR severity, concomitant valvular involvement, atrial size, left and right ventricular functions, and pulmonary arterial pressure. Transesophageal echocardiography (TEE) is valuable when the images derived from TTE are not satisfactory or when the patient is candidate for BMV to rule out clots in the left atrium (LA) and the left atrial appendage (LAA) as well as for a detailed evaluation of MR severity.

### 2.2. Hemodynamic study

Cardiac catheterization, aside from guiding the procedure, is indicated when echocardiography is nondiagnostic. It is not routinely indicated; however, it is necessary when the results from echocardiography are ambiguous, when the severity of other valvular lesions is evaluated, and when there is a suspicion of coronary artery disease. Before BMV, measurement of the mitral valve gradient, pulmonary arterial pressure, and MVA using the Gorlin equation can be helpful in borderline cases and for confirming the severity of MS.

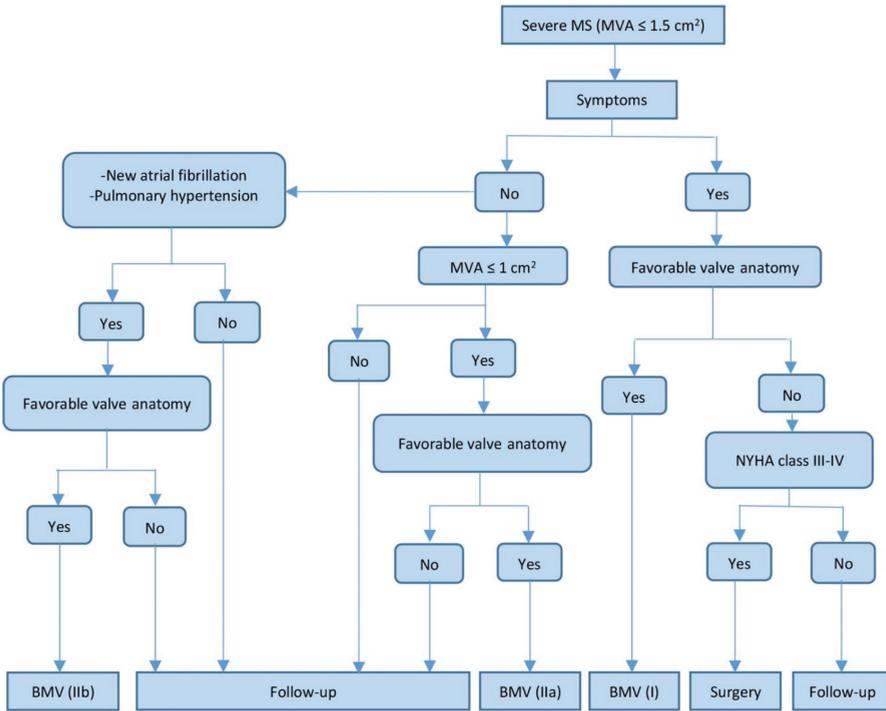


**Figure 1.** 3D echocardiography revealing bicommissural fusion, fish-mouth appearance of the mitral valve, and planimetry-derived mitral valve area of 0.89 cm<sup>2</sup>.

### 3. Patient selection

#### 3.1. Indications

BMV causes the splitting of the fused commissures and increases the MVA. Patients with symptomatic severe rheumatic MS with an MVA  $\leq 1.5$  cm<sup>2</sup> should be thoroughly evaluated and subjected to BMV if the valvular morphology is suitable [8] (**Figure 2**). Dyspnea is the most common symptom but it is not prominent in some patients. Additional attributable symptoms are exercise intolerance, fatigue, and chest pain. Given the proved long-term efficacy of BMV, even minimal symptoms should be regarded as the indication for intervention considering that this procedure is relatively safe in experienced hands. Patients with less severe obstruction (MVA  $> 1.5$  cm<sup>2</sup>) remain asymptomatic for many years and do not need non-pharmacologic intervention [9]. In addition, asymptomatic patients with very severe MS (MVA  $\leq 1$  cm<sup>2</sup>) are reasonable candidates for BMV. In patients with asymptomatic severe MS (MVA  $\leq 1.5$  cm<sup>2</sup>), BMV can be performed if pulmonary hypertension is present (pulmonary artery systolic pressure  $\geq 50$  mm Hg at rest and  $\geq 60$  mm Hg with exercise). Atrial fibrillation (AF) worsens the prognosis in patients with severe MS through deteriorating functional status, progressing structural damage, and increasing thromboembolic risk [10, 11]. Meanwhile, AF can be an indicator of progressive MS [12]. As a result, new AF in a



BMV: balloon mitral valvuloplasty; NYHA: New York Heart Association; MS: mitral stenosis; MVA: mitral valve area

Figure 2. Management of patients with severe mitral stenosis.

patient with severe MS mandates special consideration and might be an indication for BMV [8, 13]. The other potential indication for BMV is the presence of symptoms in a patient with mild MS ( $MVA > 1.5 \text{ cm}^2$ ) with the evidence of significant obstruction (pulmonary capillary wedge pressure  $>25 \text{ mm Hg}$ ) during exercise. BMV as a therapeutic option in a patient with the latter scenario should be only considered after a comprehensive hemodynamic study and the exclusion of other potential causes. In recent practice, we encounter a subset of very symptomatic old patients with severe MS and unfavorable valve anatomy who were not candidates for mitral valve replacement (MVR) because of their comorbidities. BMV might be considered in these patients, although the immediate result is suboptimal, complications are more frequent, and long-term efficacy is limited [8, 14].

### 3.1.1. Anatomic eligibility

When the patient is considered a likely candidate for BMV, morphologic characteristics should be evaluated using echocardiography. The Wilkins score comprises four echocardiographic characteristics of the mitral valve, including leaflet mobility, leaflet thickness, leaflet calcifica-

tion, and subvalvular apparatus, each given a 1- to 4-point value according to the predefined definitions [15]. Patients with Wilkins scores  $\leq 8$  are particularly suitable for BMV. This means that the mitral valve is sufficiently pliable and most often does well in response to balloon dilatation. In our practice, most patients have Wilkins scores between 8 and 10. BMV in these relatively fibrotic, rigid, and calcified valves often results in unpredictable and somehow suboptimal acute and late final MVAs, but many patients still experience acceptable and durable functional recovery, deferring eventual surgery. The ideal patients do not have MR more than moderate in severity, and the LA and LAA are free from thrombi. Significant concomitant valvular involvement including more-than-moderate aortic stenosis and regurgitation and tricuspid stenosis should not be presented. Secondary tricuspid regurgitation, even if it is significant, is not a limiting factor and most patients experience reduction in its severity after successful BMV.

### 3.2. Contraindications

When the Wilkins score is  $>10$ , BMV is generally ineffective and is, instead, associated with a higher incidence of severe MR and should, therefore, be avoided. The severity of preprocedural MR predicts the possibility of severe MR after the procedure that is associated with a poor long-term outcome of BMV. Moderate-to-severe MR ( $\geq 3+$ ) is regarded a contraindication for BMV considering that the procedure itself aggravates MR in many cases. LA thrombi or thrombi on the interatrial septum are the absolute contraindications of transseptal puncture and BMV, whereas LAA thrombi are considered a relative contraindication. Bicommisural and fluoroscopic valve calcification are associated with a poor outcome following BMV [16]. When the commissural fusion is absent, BMV is ineffective and should not be used. Many patients with MS receive oral anticoagulation because of AF. Transseptal puncture should be avoided in the presence of an International Normalized Ratio (INR)  $>1.5$  or within 4 hours after the administration of intravenous heparin. The contraindications for BMV are outlined in **Table 1**.

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Wilkins score $> 10$
Concomitant mitral regurgitation $\geq 3+$
Concomitant aortic regurgitation $\geq 3+$
Left atrial thrombus
Left atrial appendage thrombus (relative)
Severe or bicommisural calcification
Fluoroscopic valve calcification
Absence of commissural fusion
Bleeding diastasis, INR $> 1.5$
Other cardiac disease (coronary, valvular, congenital) necessitating cardiac surgery

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BMV, balloon mitral valvuloplasty; INR, International Normalized Ratio.

**Table 1.** Contraindications to BMV.

## 4. Procedure

### 4.1. Patient preparation

General considerations resemble those of the other interventional procedures. Fasting is needed for at least 8 hours for solid foods and 3 hours for liquids. The patient should be hydrated according to the standard protocols for the prevention of contrast-induced acute kidney injury. BMV and even transseptal catheterization can be performed with no or minimal contrast media; accordingly, contrast-induced nephropathy is not a major issue. Rapid heart rate in patients with AF might interfere in stable balloon dilatation and should be controlled. No specific pharmacologic pretreatment is needed before BMV, but most medications (beta-blockers, calcium channel blockers, digoxin, etc.) are routinely continued. Warfarin should be withheld for 3 days before the procedure. Instead, heparin is needed to be infused while the patient is under therapeutic INR levels ( $\text{INR} < 2$ ). Heparin infusion is stopped 4 hours before the patient arrives at the catheterization laboratory. Preprocedural TEE is of paramount importance to exclude LA/LAA thrombi in all patients and should be performed preferably just before but not more than 2 weeks before BMV because the possibility of LA/LAA clot cannot be completely ruled out even with sinus rhythm. Antibiotic prophylaxis is not routinely prescribed before or during the procedure, but it might be needed if the aseptic barrier has been disrupted.

### 4.2. Anesthesia

Most BMV procedures can be performed under mild conscious sedation. Rarely, the patient has a tender septum and experiences discomfort during the transseptal puncture and might need analgesia and more sedation and exceptionally, general anesthesia. General anesthesia is also needed in uncooperative or unstable patients or when TEE is used to guide transseptal catheterization and BMV in difficult cases.

### 4.3. Approaches

The antegrade transvenous transseptal approach is most commonly used. The right femoral vein is preferred because appropriate alignment of the transseptal needle with the interatrial septum facilitates septostomy. The left femoral and rarely jugular veins also can be used [17, 18]. The femoral or radial arteries are used for hemodynamic monitoring, performing catheterization, and guiding the transseptal puncture. The retrograde non-transseptal approach from the femoral artery has been utilized with acceptable results; nonetheless, higher risks of arterial damage and more hemodynamic burden arising from the trans-aortic passage of the balloon catheter have limited its use [19].

### 4.4. Transseptal puncture

It is the first and very important step in performing a successful BMV. The transseptal puncture is the source of complexity and complications in many patients undergoing BMV. Although

the puncture site is less important than that in the MitraClip and LAA occlusion, a central or slightly low puncture is recommended. An appropriate puncture site facilitates the crossing of the mitral valve by the balloon catheter. A low puncture is especially important when the double balloon or metallic commissurotome is used. Fluoroscopy is the fundamental imaging tool used to guide the transseptal puncture but TEE and intracardiac echocardiography (ICE) can help in difficult cases or for performing a site-specific puncture.

## 4.5. Techniques

Thus far, several techniques have been introduced. Of those, the Inoue balloon technique has gained the most popularity because of its safety and effectiveness.

### 4.5.1. *Metallic commissurotome*

A reusable metallic dilator has been developed to decrease the cost of the procedure. It has been reported that the procedure is safe, with good acute and long-term results comparable to the Inoue technique [20]. The risk of LV perforation and subsequent tamponade with the metallic device should be considered. The more demanding nature of the procedure and concerns about the reused devices have limited this technique in many countries.

### 4.5.2. *Double balloon technique*

In this antegrade transseptal technique, a balloon-tipped catheter is used to cross the mitral valve followed by introducing an exchange-length (260 cm) wire through the catheter lumen securing its end in the LV or the descending aorta. A second wire should be introduced by the same way or using a dual-lumen catheter. Two balloons (15–20 mm in diameter) are introduced over the wires and positioned across the mitral valve and inflated simultaneously [21]. In theory, two balloons side-by-side can exert a more focused pressure on the commissures than a single balloon. This technique is relatively safe and effective but is not widely used because of being more time-consuming than the Inoue technique and more hazardous because of the risk of wire-induced LV perforation. The multi-track system is a newer variant of double-balloon valvuloplasty that provides effectiveness of double-balloon inflation using a single wire.

### 4.5.3. *Inoue balloon technique*

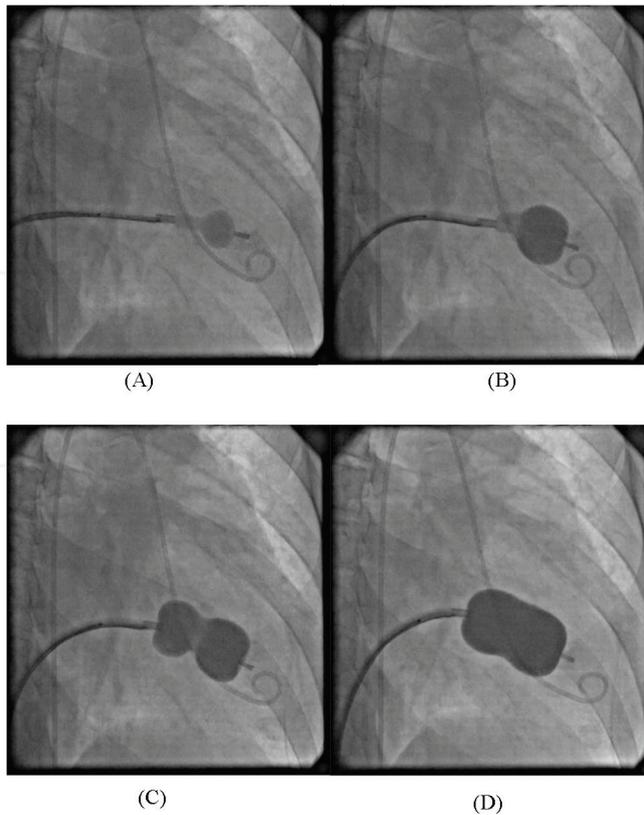
The Inoue balloon catheter is a dumbbell-shaped balloon that self-positions in the mitral valve because of its unique physical properties and mode of inflation. It has been made from two latex layers and a middle nylon layer, giving the balloon its specialized shape and inflation characteristics. The balloon inflates in three sequential stages. The distal end of the balloon inflates at the first stage, followed by the proximal half, to facilitate positioning across the mitral valve. Finally, inflation of the waist portion of the balloon separates commissures [22]. Several balloon sizes are available (24, 26, 28, and 30 mm in diameter), and each can be inflated in a 4-mm diameter zone. The reference balloon size (RS) is calculated based on the height of the patient (patient's height in cm rounded to the nearest 0, divided by 10, and 10 added to

the ratio) or the newly introduced method of inter-commissural diameter [23–25]. In patients with pliable valves, an RS-matched balloon is selected but in patients with pre-existing MR, severe commissural calcification, significant subvalvular involvement, or very severe MS ( $MVA \leq 0.5 \text{ cm}^2$ ), as well as in patients with special situations where they do not need very large valve areas or in patients whose complications are more common and difficult to manage (i.e., old patients, pregnancy, etc.), a balloon 1 size smaller than the RS is chosen [23].

Immediately after the transeptal puncture, confirming the position of the needle tip in the LA and septal dilation, 70–100 IU/kg of heparin is administered intravenously to achieve an activated clotting time (ACT) of 250–300 s. A spring pigtail-like stiff wire is placed in the LA and a 14-French dilator is used to dilate both the femoral subcutaneous track and the atrial septum. A previously vented, de-aired, and calibrated slenderized balloon is sent to the LA over the wire and then reshaped to its original deflated configuration by removing the stretching tube and the wire and pulling back the gold tube. If there is any resistance when crossing the inguinal area, redilating the area using a larger dilator definitely helps. To overcome the resistance across the septum, the operator turns the balloon catheter in one or other directions or dilates the septum with a peripheral balloon (6–8 mm in diameter). By changing the projection from the anteroposterior (AP) to the right-anterior oblique (RAO), the operator introduces the stylet and while the balloon is partially inflated at its distal end acting as a floating balloon, the operator directs the balloon catheter toward and across the mitral valve with a combination of rotating anticlockwise and pulling the stylet and pushing the balloon. Free movement of the balloon in the LV toward the apex shows that the balloon has not been entrapped in the subvalvular apparatus and papillary muscles. In the final step, the distal half is fully inflated and the balloon is retracted to catch the mitral valve, followed by the inflation of the proximal and central part of the balloon until the disappearance of the waist (**Figure 3**). If any kind of distortion in the contour of the balloon is seen, the inflation should not be continued because of the possibility of balloon entrapment and subsequent severe MR. The balloon should be inflated with a diluted contrast medium (contrast-saline ratio of 1:5) to minimize the inflation-deflation period (2–4 s). It is recommended that the balloon be inflated in a stepwise fashion started 2–4 mm below the calculated RS. The balloon size is then increased 1 mm in each step, and the procedure should be stopped if any of the following criteria is met: (1) final MVA  $>1.5 \text{ cm}^2$  or an increase in the valve area of 50%, (2) a fall in the mean gradient by 50% or from  $>10$  to  $<5 \text{ mm Hg}$ , (3) complete opening of at least one commissure, and (4) appearance or aggravation of MR  $>1+$  (**Table 2**).

#### 4.6. Surveillance of the procedure

Imaging modalities combined with fluoroscopy can help to guide the procedure, assess the results, and diagnose complications. Evaluation of the mean LA pressure, transmitral valve gradient, and the contours of LA pressure between the inflations might help but they are subjected to variations and are not reliable markers of the success or occurrence of the complications. In addition, the MVA, estimated by the Gorlin formula, is affected by atrial shunt and MR. TTE is integral to guiding the procedure and should be performed between the inflations and at the end of BMV. The planimetry-derived MVA, splitting of the commissures, and the severity of MR can be readily and reliably assessed in many patients



**Figure 3.** Inoue technique. Inflation of distal end of the balloon, retracted toward mitral valve (A–B). Inflation of proximal half catching the commissures in between (C). Full inflation of the balloon disappearing the waist (D).

using TTE. TEE needs general anesthesia and is difficult to perform in the catheterization laboratory but is helpful in patients with poor echo window and in pregnant women in whom fluoroscopy is of concern. The TEE also provides superior views to verify the positioning of the balloon in the mitral valve in difficult cases (**Figure 4**).

#### 4.7. Postprocedural considerations

After the removal of the balloon catheter, the venous access site should be compressed to achieve hemostasis. The arterial access is managed depending on the site (femoral or radial). The patient should be monitored overnight in a step-down unit to detect complications. Most patients can be discharged within 1–2 days. In patients with AF, heparin can be restarted 3–4 hours after sheath removal, followed by warfarin. Bedside TTE can detect late accumulation of pericardial effusion. The patients who have developed complications need to be closely monitored in the intensive care unit. The PHT is affected by the change in compliance immediately after BMV; therefore, it is recommended to calculate the MVA by the PHT 2–3

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 Balloon reference size (RS)

- $0.1 \times \text{height (cm)} + 10$  (after rounding the patient's height to the nearest zero) or
- 30 for height  $>180$  cm, 28 for 160–180 cm, 26 for  $<160$  cm or
- Inter-commissural diameter measured on parasternal short-axis echocardiogram view

## Balloon size selection

- RS-matched if the patient is young, valve is pliable, and MR is absent or less than 1+
- 1 size smaller than the RS if the valve is rigid, MR is  $>1+$  and in high risk subjects (i.e., pregnancy, old age)

## Inflation mode

- Start 2 mm below the RS in low risk patients, 4 mm in high risk patients
- Inflate in 1 mm increments under echocardiographic guidance

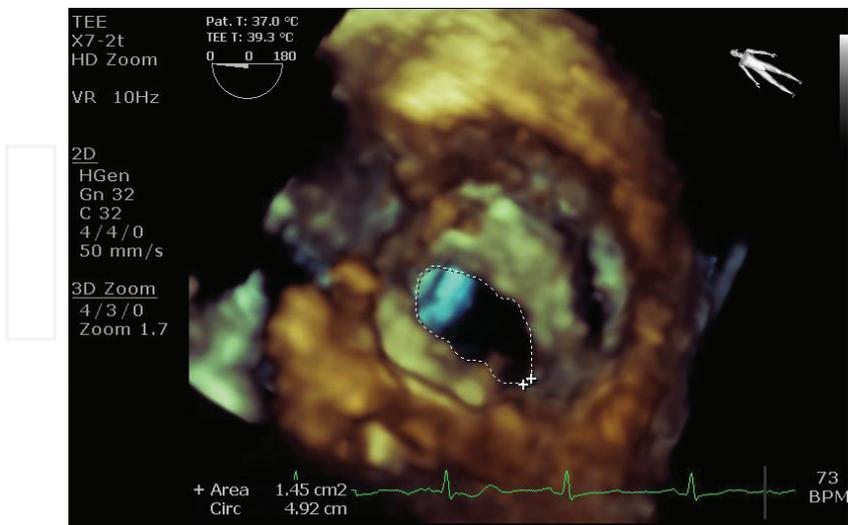
## Closing criteria

- $\text{MVA} > 1.5 \text{ cm}^2$
  - 50% increase in the MVA
  - 50% fall in mean gradient
  - Fall in mean gradient from  $>10$  mm Hg to  $<5$  mm Hg
  - Appearance or aggravation of MR  $> 1+$
  - Complete opening of at least one commissure
- 

MR, mitral regurgitation; MVA, mitral valve area; RS, reference size.

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**Table 2.** Inoue balloon selection and inflation protocol.



**Figure 4.** Postprocedural 3D imaging of the mitral valve revealing final mitral valve area of  $1.45 \text{ cm}^2$ .

days later. Direct planimetry yields the most accurate estimate of postprocedural MVA, but it might overestimate the MVA in the first day after the procedure and should be performed 1–2 days later allowing for the early loss [26]. TEE is not routinely recommended after successful BMV. If there is severe MR, TEE is essential for detecting its exact mechanism, which is important for further decision regarding conservative or invasive intervention.

## 5. Complications

General complications (i.e., vascular injury, arrhythmias, and contrast allergy) might occur and should be managed accordingly. Mortality has been reported in 1–2% and is mainly due to cardiac tamponade or the poor underlying condition of the patients [27].

### 5.1. Cardiac perforation and tamponade

Hemopericardium is the main complication of BMV and is seen in 1% of patients. The transseptal puncture is the source of most cardiac perforations during BMV. The anatomic factors of patients such as atrial enlargement and chest deformities increase the risk. TEE and ICE can guide the transseptal puncture, especially when the operator is inexperienced or in difficult cases, and reduce the risk of hemopericardium. Double-balloon mitral valvuloplasty and metallic commissurotome are associated with the risk of LV perforation because the wires are handled in the LV cavity. The management depends on the severity of pericardial effusion and the mechanism and consists of closed observation, reversal of heparin, pericardiocentesis, and emergent surgery. When the hemopericardium happens after septal dilation or LV perforation, especially if it is retractable despite prompt drainage, surgery is necessary to be proceeded.

### 5.2. Systemic embolism and stroke

While BMV might decrease the long-term risk of systemic embolism in patients with MS, the procedure itself can be associated with embolic stroke in about 1–1.5% of patients [28]. Meticulous anticoagulation and de-airing of the equipment and preprocedural TEE to rule out LA thrombi will reduce the chance of systemic embolism. An undiagnosed pre-existing LA/LAA clot and thrombus formation during the procedure are the main mechanisms, but calcium or air embolism also has a role.

### 5.3. Severe MR

Commissural opening, which is the main mechanism of increasing the MVA, is associated with aggravating MR after BMV in many patients but most are not significant and usually do not worsen functional status and long-term prognosis of the affected patients. Severe MR occurs in 2–15% of patients mainly because of non-commissural valve tearing and chordal rupture but exaggerated commissural splitting and rarely papillary muscle rupture are responsible [27, 29–31]. The incidence of severe MR does not change with different techniques

(Inoue vs. double balloon and metallic commissurotomy) [20, 32]. Unfavorable valve anatomy and inappropriate balloon sizing and inflation protocol predict the occurrence of severe MR after BMV, but their predictive value is not high and it can occur unpredictably in some patients with good morphologic features. Most patients need subsequent mitral valve surgery (mostly MVR) because severe MR is associated with the deterioration of functional status and poor outcomes. The timing of the surgery is determined by clinical tolerance, hemodynamic stability, mechanism of MR, and surgical risk. Most patients with severe MR can be managed conservatively and are subjected to mitral valve surgery on a scheduled basis. In a small number of patients who remain severely symptomatic despite initial medical therapy or who experience hemodynamic instability, or when the mechanical background of MR is severe and irreversible, urgent MVR should be planned. Patients with moderate MR can be often followed-up for a long period of time and some even experience a reduction in the severity of MR over time [33, 34].

#### **5.4. Atrial septal defect**

A wide range of frequency has been reported (10–90%) depending on modality that has been used for detection [35, 36]. Most defects decrease in size or disappear over time and have no adverse effects [37]. Infrequently, the defect is large enough to cause significant left-to-right shunting, especially when there is a significant residual mitral valve gradient and, therefore, surgical repair should be performed along with mitral valve surgery. Percutaneous closure of post-BMV residual atrial septal defects has not been reported and seems to be unsuccessful. In rare circumstances, right-to-left shunting and subsequent paradoxical embolism might happen in patients with significant pulmonary hypertension.

#### **5.5. Emergent surgery**

Rarely, patients need emergent surgery because of the complications. The most frequent cause is hemopericardium unresponsive to pericardiocentesis, especially when it happens after septal dilation and LV perforation. In most patients, the surgery includes repair of the tearing and MVR. Severe MR can also necessitate urgent surgery in some patients.

## **6. Special considerations**

### **6.1. LAA/LAA thrombus**

If the patient is clinically stable, BMV can be postponed for 3–6 months, while the patient receives intensive anticoagulation with an INR of 3–3.5. If repeated TEE shows that the clot has been completely resolved, BMV can be safely performed. If the thrombus persists, the patient should be referred for open mitral valvulotomy or MVR. If surgery is not a feasible option, BMV is not possible to be deferred, and the thrombus is small, fixed, and confined to the LAA, experienced operators might do BMV ensuring that the wire and balloon catheter are kept away from the LAA.

## 6.2. Previous valvulotomy

Restenosis is not infrequent after percutaneous or surgical commissurotomy. As a growing population, these patients account for one-third of all MS patients in developed countries. Depending on the mechanism, commissural fusion is not predominant in some cases, which limits the role of BMV as an effective intervention. BMV is a feasible option in patients with significant restenosis after percutaneous, closed, or open valvulotomy as long as the commissural fusion is present and valve anatomy is favorable [38]. Immediate and mid-term results are encouraging but might be slightly less satisfactory than with *de novo* MS.

## 6.3. Pregnancy

Significant hemodynamic burden caused by pregnancy, labor, and delivery might be not well-tolerated by patients with severe MS. Patients with severe MS often experience worsening of the symptoms or become symptomatic for the first time during pregnancy. Not surprisingly, MS is detected for the first time in many patients during pregnancy. If left untreated, severe MS is associated with a high maternal and perinatal mortality, not least in those who are highly symptomatic or have AF. The intrapartum and postpartum period carries the highest risk in these patients [39]. In patients who remain symptomatic, despite medical therapy, BMV should be performed because the surgery is associated with very high risk of fetal death [40]. BMV is an effective and safe method for relieving MS in pregnant women when performed by highly experienced operators. It has been reported that BMV during pregnancy has a high success rate and excellent short-term results and provides normal eventless deliveries in the majority of patients. In addition, stillbirth is infrequent and most babies have normal growth and developmental patterns [41, 42]. From a practical point of view, to avoid radiation during organogenesis, the procedure should be performed after the 12th week or ideally after the 20th week. The lead shields should cover the abdomen and pelvis and behind the patient. Fluoroscopy time should be minimized as much as possible. The Inoue balloon technique seems to be the preferred method considering shorter fluoroscopy time and inflation-deflation cycle of the balloon. Special care should be taken about the gravid uterus, possible difficulties in the passage of the equipment through the compressed inferior vena cava, and the chance of hypotension and subsequent fetal distress when the mother lies for a long period of time. The balloon size should be selected with great caution. A balloon 1 size smaller than the RS-matched is preferable in borderline cases. The more conservative method of measuring the inter-commissural diameter can be used for balloon sizing in these patients. The stepwise balloon dilatation of 0.5 mm is advisable, and aggressive balloon dilatation is necessarily avoided because it might result in severe MR and subsequently needs urgent surgery, which is unacceptably hazardous to mother and child. TEE can assist in the transseptal puncture, balloon positioning, and stepwise inflations and can limit fluoroscopy time. However, it needs general anesthesia in many cases, requiring that the position of the patient be changed to lateral decubitus to prevent hypotension in prolonged procedures.

## 6.4. Inoperable patients

BMV might be an option in patients who are old and have significant comorbidities. Given the suboptimal results and the higher incidence of complications arising from unfavorable morphologic characteristics of the mitral valve and poor condition of patients, BMV should be only used in highly symptomatic patients. In these patients, a more conservative BMV strategy is suggested. The Inoue technique is more appropriate because it is less demanding and provides a faster and smoother procedure. A balloon 1 size smaller than the RS is chosen, followed by a further stepwise dilatation of 0.5 mm. The final result should be judged on an individualized basis. Definitely, a smaller MVA is sufficient in most patients in exchange for severe MR and the difficulty in its management.

## 7. Results

### 7.1. Immediate results

A good immediate result is defined as an MVA  $> 1.5 \text{ cm}^2$  without MR more than moderate and is most probably achieved in patients with favorable morphologic features; nonetheless, other factors including age, history of previous commissurotomy, smaller baseline MVA, pre-existing MR, pulmonary artery pressure, sinus rhythm, functional status, and technical issues are also determining [43, 44].

### 7.2. Long-term results

When BMV has a good acute result, the long-term survival rate is high and the need for reintervention is infrequent. Anatomical characteristics and age are important predictors of long-term outcomes. Midterm outcomes (3–7 y) are favorable and comparable with open mitral valvulotomy and better than closed mitral valvulotomy [5].

Restenosis can occur after successful BMV, but its incidence is difficult to determine due to the absence of a uniform definition and different follow-up periods in the studies. An MVA  $< 1.5 \text{ cm}^2$  or a 50% loss in the initial MVA is generally defined as restenosis. The possible mechanisms include suboptimal initial results, recurrent rheumatic attacks, and a hemodynamic-related degenerative process. In patients with symptomatic severe restenosis, repeat BMV or mitral valve surgery should be selected according to the guidelines.

## 8. Conclusions

MS as the long-standing sequel of RHD is rare in developed countries, whereas it is still seen frequently in many areas of the world. BMV as a minimally invasive transcatheter technique is the method of choice in the treatment of these patients. In successful cases, BMV results in a very high survival rate and freedom from symptoms. Appropriate patient selection and a competent technique are the key factors for achieving an excellent result.

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