# Percutaneous Mitral Valvuloplasty—A New Method for Balloon Sizing Based on Maximal Commissural Diameter to Improve Procedural Results

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**Background:** Since the introduction of the Inoue technique for percutaneous balloon mitral valvuloplasty (PBMV), various criteria have been proposed for ideal balloon sizing. In routine practice, balloon size is chosen based on the patient's height according to a simple formula. We tried to define a simple and practical echocardiographic measure for adjusting balloon catheter size to achieve better success rates and fewer complications. **Methods:** Patients with moderate to severe mitral stenosis who were candidates for PBMV were selected. Maximal mitral commissural diameter at a fully opened state during diastole was measured by transthoracic echocardiography and compared with the values from the height-based formula. Data were compared by paired sample t-test. **Results:** Eighty-three patients (mean age 45±13.2 years; 77 female) participated. The median balloon size was 28mm (standard deviation [SD] 1.2) according to the height-based formula and 26mm (SD 1.6) according to echocardiography ($p<0.001$). Using a Bland-Altman plot, an excellent agreement was observed between the two methods. Regression models were fitted to estimate the balloon size using the patients' height, commissural diameter, and mitral valve score. **Conclusion:** Selection of balloon size according to echocardiographic commissural diameter is a good alternative method. Assuming the possible discrepancy between height-based and commissural-based estimated balloon sizes in some cases, adjustment of balloon sizes according to the maximal commissural diameter may result in acceptable results and fewer complications.

Despite a dramatic fall in the incidence of rheumatic fever (RF), it continues to affect young people and is one of the main causes of acquired heart disease in developing and underdeveloped countries.[1] Rheumatic heart disease including mitral stenosis (MS) is one of the late manifestations of RF that could potentially result in debilitating symptoms and complications. After the advent of percutaneous therapeutic procedures, balloon mitral valvuloplasty (BMV) using the Inoue technique gained popularity and currently is the procedure of choice for treatment of rheumatic MS in patients with favorable valve anatomy.[2] In these patients long-term outcome is favorable, with excellent survival rates without functional disability or need for repeat intervention.[3,4] By contrast, the results of BMV in those with adverse valve morphology are less predictable.[5–8]

Selection of an appropriately sized balloon catheter for a safe stepwise dilation procedure is of paramount importance in order to avoid iatrogenic severe mitral regurgitation (MR) during BMV. Various criteria have been proposed for ideal balloon sizing, depending on the patient's height,[9,10] body surface area (BSA), and mitral annulus size.[11–13] Current guidelines for selection of balloon catheter are based on balloon reference size, which is derived from the patient's height, the transthoracic echocardiographic characteristics of the mitral valve, fluoroscopic presence of valvular calcification, and degree

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**Figure 1. Maximal Diameter of Mitral Valve at Fully Opened State During Diastole**

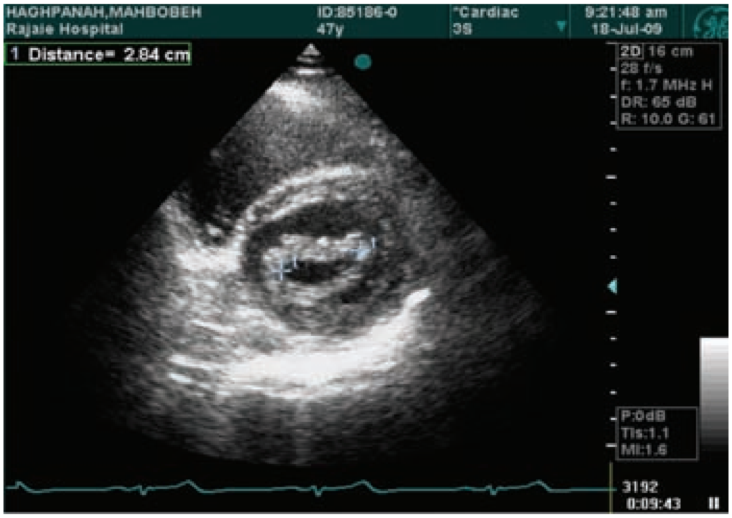


**Table 1: Patients' Background Data**

| | Descriptive Statistics | Range |
|---|---|---|
| Age (years) | 45±13.1 | 14–71 |
| Female/male | 77/6 | – |
| Height (cm) | 160±7.6 | 147–186 |
| Weight (kg) | 64±12.5 | 43–90 |
| BSA (m²) | 1.66±0.17 | 1.37–2 |
| LVEF (%) | 55±6 | 25–65 |
| LA area (cm²) | 28.2±4.2 | 21–35 |
| Annulus diameter (mm) | 30±2.6 | 25.2–43 |
| Score | 86±1.1(median = 9) | 5–11 |
| Thickness | 2.2±0.46 | |
| Calcification | 1.96±0.44 | |
| Mobility | 1.99±0.27 | |
| Sub-valvular | 2.5±0.53 | |
| Atrial fibrillation | 31 (37.3%) | – |

*BSA = body surface area; LA = left atrium; LVEF = left ventricular ejection fraction.*

**Table 2: Patient Characteristics Before and After Balloon Mitral Valvuloplasty**

| | Before BMV (n=83) | After BMV (n=83) | |
|---|---|---|---|
| Mitral valve area (cm²) | 0.89±0.16 | 1.38±0.30 | p<0.001 |
| Transmitral valve gradient (mmHg) | 11.6±6.5 | 2.3±2.8 | p<0.001 |
| Mitral regurgitation | | | p=0.11 |
| None | 44 (53%) | 40 (48.2%) | |
| Mild | 33 (39.8%) | 30 (36.2%) | |
| Moderate | 6 (7.2%) | 8 (9.6%) | |
| Severe | 0 (0%) | 5 (6%) | |

*BMV = balloon mitral valvuloplasty.*

of angiographic MR before the procedure. Today, balloon size is conventionally chosen based on the patient's height according to a simple formula: size = 0.1 x height + 10.[14–16] As there are occasional unsatisfactory results with height-matched balloon sizes, including residual transmitral valve gradient (undersizing) or MR (oversizing), it seems logical to look for another way to refine the formula in order to achieve more desired outcomes.

The aim of the current study was to define a simple and practical echocardiographic measure for appropriate balloon catheter sizing. In this study we compared balloon sizes from the conventional formula with those from echocardiographic measurement of maximal commissural diameter, which is the smallest balloon size required to open a commissural fusion.

## Methods

**Patient Selection.** We selected 83 consecutive patients with moderate to severe MS and favorable valve anatomy who were indicated for BMV because of related clinical symptoms or echocardiographic findings.

**Echocardiography.** In addition to the usual studies—such as measurement of mitral valve area (MVA), Wilkins score and its components, presence or absence of left atrial thrombus, and severity of MR using transesophageal echocardiography—maximal mitral commissural diameter at a fully opened state during diastole was measured in short-axis view using transthoracic echocardiography in all patients (see *Figure 1*).

**Mitral Valvuloplasty.** Balloon sizes were calculated via the conventional height-based formula and BMV was performed using recommended standards. The severity of MR was assessed angiographically before and after the procedure. Procedural success was defined as post-procedural MVA ≥1.5cm², at least a 50% decrease in transmitral valve gradient, and a final gradient <5mmHg.

**Statistical Analysis.** Data were described as mean ± standard deviation (SD) for interval and count (percent) for categorical variables. Comparison between the data before and after the BMV was performed by paired t or Wilcoxon signed-rank tests. A p-value <0.05 was considered statistically significant. Agreement between the two methods of estimation was investigated by Bland-Altman plot. Simple and multiple linear regression models were fitted to estimate the balloon size. SPSS 15 for Windows (SPSS Inc. Chicago, Illinois) was used for statistical analysis.

## Results

**Patient Characteristics.** Eighty-three patients (77 women; mean age 45±13.2 years, range 14–71 years) participated. Mean left ventricular ejection fraction (LVEF) was ~55±6%. Before BMV, the mean MVA was 0.89±0.16cm² and mean transmitral valve gradient (TMVG) was 11.6±6.5mmHg. The median valve score was 9 (range 5–11). Eighteen patients (20%) had a history of previous BMV or surgical mitral commissurotomy. Additional data are presented in *Tables 1* and *2*. After the procedure, significant changes were observed in the patients' medical characteristics (see *Table 2*). BMV was assessed as successful in 71 patients (85.5%), but there was newly acquired MR or aggravated MR in eight patients.

**Selection of Balloon Diameters.** The mean commissural size in study patients was 25.8±2.8mm. The mean estimated balloon size was 25.9±1.5mm according to height and 25.8±2.8mm based on commissural size. The median balloon size was 28mm (SD 1.2) according to the height-based formula and 26mm (SD 1.6) according to echocardiography (p<0.001). The height-based formula estimated the sizes as being greater and echocardiography estimated the sizes as being smaller than the real balloon sizes (the final sizes used during BMV). These differences were statistically significant, but clinical importance needs to be defined. According to the patients' need, the average size of balloons used during BMV (real size) was 26mm (range 24–30mm). The mean difference between the sizes estimated by the height-based formula and the real size was 0.81±1.2mm; on the other hand, the mean difference between the balloon sizes estimated by echocardiography and the real size was 0.84±2.1mm.

The agreement between the sizes estimated by the patients' height and echocardiography was investigated using a Bland-Altman plot (see *Figure 2*). An excellent agreement was observed between the two methods in estimating the real size of the balloons used in patients.

We tried to fit statistical models to estimate the real balloon size based on the study data (see *Table 3*). Using the patients' height and fitting a simple linear regression model, a new height-based formula was created. Instead of the previous equation (size = 0.1 x height + 10), we should use the new formula: size = 0.08 x height + 14.1 ($r^2$=0.16). Also, we decided to enter the mitral valve score into the model (see *Table 3*). The results showed that the $r^2$ was increased using this complementary model ($r^2$=0.32), which means more precise estimates can be made. On the other hand, according to echocardiographic data, the $r^2$ of the simple model is very small ($r^2$=0.001) and of the complementary model is 0.16; thus, when using the echocardiography method, only the complementary model should be applied for estimation of balloon size.

**Figure 2: Bland-Altman Plot Showing Excellent Agreement Between the 'Height Formula' and Echocardiography for Estimation of Balloon Size**

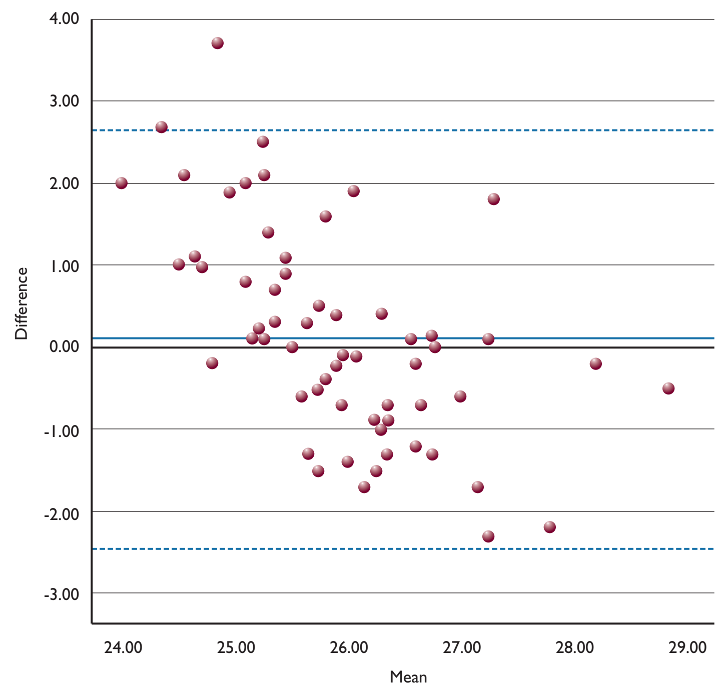


**Table 3: Equations for Estimation of Actual Balloon Size**

| Model's Name | Description | $R^2$ |
|---|---|---|
| Height-based estimation | | |
| Simple | 0.08 x height + 14.1 | 0.16 |
| Complementary | 0.09 x height + 0.5 x score + 8.2 | 0.32 |
| Echocardiography-based estimation | | |
| Simple | 0.03 x commissural diameter + 25.6 | 0.001 |
| Complementary | 0.25 x commissural diameter + 0.49 x score + 15.7 | 0.16 |

## Discussion

Inoue balloon size has long been selected according to the conventional formula and reported data seem to be acceptable in terms of immediate and long-term results. However, the question is: 'Can a single formula meet all variations?' We assumed that maximal commissural diameter at transthoracic echocardiography is the smallest balloon size required to open commissural fusion. Although the balloon sizes derived from these methods were not exactly equal, to overcome the calibration problem we adopted the Bland-Altman method, which showed a good agreement between the two measurements. Therefore, commissural diameter by echocardiography appears to yield a measure of Inoue balloon size that is as good as the conventional height-based formula (see *Figure 2*). The power of this measure seems to be increased by entering the mitral valve score into the model. This controversy may result from the small sample size of this study, and a higher-powered randomized trial might show the direct effects of these measurements on patients. The adoption of this new method would be especially worthwhile in cases with a great difference between the balloon sizes estimated by the two methods, such as those in our study (2.4%) in whom commissural diameter suggested a remarkably smaller balloon size than that selected via height, and those who experienced severe MR following standard BMV. Of note, two of seven cases who suffered from severe MR after the procedure were those with a condition we named 'height–commissure mismatch.' It can be postulated that although selecting BMV balloon size using the height-based formula is a reasonable and relatively safe method, adjustment of balloon sizes according to the commissural diameter—especially in those with considerable discrepancy between height-based versus commissural-based estimated balloon sizes—may result in even fewer cases of significant MR due to oversized ballooning. ■

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