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Doctor of Medicine

**Determination of Inoue Balloon Size by Analysis of Mitral Valve
Geometry using Three-Dimensional Transesophageal
Echocardiography in Patients with Mitral Stenosis**

승모판 협착증 환자에서 삼차원 경식도 심초음파 영상의
승모판막 형상 분석을 통한 이노우에 풍선 크기의 결정

**The Graduate School
of the University of Ulsan
Department of Medicine
Mi-Jin Kim**

**Determination of Inoue Balloon Size by Analysis of
Mitral Valve Geometry using Three-Dimensional
Transesophageal Echocardiography in Patients with
Mitral Stenosis**

Supervisor: Jong-Min Song

A Doctoral Dissertation

**Submitted to
the Graduate School of the University of Ulsan
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by

Mi-Jin Kim

**Department of Medicine
University of Ulsan, Korea**

February 2024

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This certifies that the dissertation of Mi-Jin Kim is approved

Committee Chairman Professor Duk-Woo Park

Committee Member Professor Jong-Min Song

Committee Member Professor Dae-Hee Kim

Committee Member Professor Jung-Min Ahn

Committee Member Professor Yong-Jin Kim

**Department of Medicine
University of Ulsan, Korea
February 2024**

ABSTRACT

Background: Percutaneous mitral balloon commissurotomy (PMBC) is recommended as an initial treatment in patients with mitral stenosis (MS) and favorable valve morphology. Determining the appropriate balloon inflation size is a critical step in this percutaneous procedure. We aimed to evaluate the clinical value of balloon size selection based on the quantitative analysis of mitral valve (MV) geometry determined by 3D transesophageal echocardiography (TEE).

Methods: A total of 184 consecutive patients who underwent PMBC for significant MS were retrospectively analyzed. MV annulus geometry was analyzed during mid-diastole, including lateral-medial diameters obtained from dedicated 3D software (LMD-3d) or from analysis using multiplanar reconstruction image (LMD-mpr). Patients were categorized into three groups based on the PMBC results; those with successful results as Group SU, those with remnant mitral stenosis as Group MS, and those with significant MR as Group MR.

Results: Group SU, MS, and MR consisted of 110, 50 and 17 patients, respectively. We compared three conventional formulas (Formula 1,2,3) for determining balloon size based on the patient's height or body surface area with two new formulas derived from mitral valve geometry using linear regression analysis in Group SU: balloon size = $0.0684 \times \text{LMD-3d} + 24.309$ (Formula 4) and $0.061 \times \text{LMD-mpr} + 24.573$ (Formula 5). Compared with the calculated balloon using formula 4, the inflated balloon sizes used in Group MS were significantly smaller (-0.78 ± 1.02 ; $p < 0.001$), while those used in Group MR were significantly larger (0.56 ± 1.05 ; $p = 0.04$). This pattern was consistent in formula 5 as well.

Conclusions: Selecting the Inoue balloon inflation size based on the mitral annulus diameter determined by 3D TEE might be a reasonable approach. Further prospective study is warranted to validate the clinical benefit of the formulas derived from this study.

Key word: mitral stenosis, percutaneous mitral balloon commissurotomy, transesophageal echocardiography

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Introduction

Mitral stenosis (MS) is mostly caused by rheumatic fever and still one of the common valvular heart diseases in developing countries, although both the incidence and the prevalence of rheumatic MS have seen a decrease in recent years. MS still results in significant morbidity and mortality worldwide,¹⁻⁴ and symptomatic MS, if left untreated, has a poor prognosis.^{2,5} Therefore, the ACC/AHA and ESC guidelines have recommended percutaneous mitral balloon commissurotomy (PMBC) as an initial treatment in patients with symptomatic MS and favorable valve characteristics.^{6,7}

Although the immediate and late success rate of PMBC using Inoue balloon is high and its safety and effectiveness is well established, ineffective opening of mitral valve (MV) or post-procedural significant mitral regurgitation (MR) occurs. Furthermore, mitral valve rupture is a rare but serious complication requiring emergency surgery.⁸⁻¹⁰ Determining balloon inflation size is one of the critical steps in this percutaneous procedure. However, balloon size has been determined by a crude method, which is based on the patients' height or body surface area (BSA).¹¹

A few studies have demonstrated that the selection of Inoue balloon size based on the maximal annulus diameter measured using two-dimensional (2D) transthoracic echocardiography (TTE), was an effective and safe method.^{12,13} However, the mitral annulus has a noncircular and saddle shape, measuring its diameter using 2D TTE has inherent limitations and is subject to measurement errors. Recent technological developments in three-dimensional (3D) transesophageal echocardiography (TEE) have enabled more precise visualization and accurate measurement of MV geometry.¹⁴ However, there has been no study to demonstrate the clinical benefit of determining the appropriate balloon size for PMBC using 3D TEE. Therefore, we aimed to investigate on the feasibility of balloon size selection based on the quantitative analysis of MV geometry analyzed using 3D TEE.

Methods

Patient population

We retrospectively identified consecutive patients who underwent PMBC using Inoue single-balloon technique for significant MS between March 2018 and July 2022 in the Asan Medical Center. The exclusion criteria were as follows: (1) absence of baseline 3D echocardiographic images, (2) patients who had suboptimal 3D TEE image, and (3) significant MR before PMBC. The Institutional Review Board of our hospital approved this study protocol, and the need for informed consent was waived considering the retrospective nature of the study. Our investigations were carried out in accordance with the Declaration of Helsinki.

Clinical and echocardiographic data

Baseline clinical characteristics and echocardiographic characteristics were reviewed from medical records. Before PMBC, all patients had undergone 2D TTE, and 2D- and 3D-TEE using an EPIQ ultrasound machine and a 3D matrix array 2.7 MHz TEE probe (Philips Medical Systems, Andover, MA). The 3D full-volume images were acquired and ECG-gated full-volume data sets were collected over 2 cardiac cycles. Care was taken to include the whole MV and mitral annulus in a full-volume image, and the images were obtained after the gain, compression controls, and time gain compensation settings were optimized to ensure image quality. The MV geometry was analyzed during mid-diastole using dedicated software (QLab13, Philips Andover, MA and Tomtec imaging system, GMBH, Munich, Germany). All measurements of 3D TEE images were independently conducted without knowing the 2D results. In a series of 2D projection planes generated from the 3D data set, the annulus and leaflets were traced manually using QLab software. After the delineation of the annulus and leaflets on the mid-diastole frame of the cardiac cycle, the software generated a 3D model of the valve and automatically measured the various parameters of annular and leaflet geometry,

including mitral annulus lateral-medial diameter (LMD-3d) which is commissure-commissure diameter, antero-posterior diameter (APD-3d), 2D and 3D mitral annulus area and annulus height (**Figure 1A**). In addition, on multiplanar reconstruction (MPR) images using Tomtec software, the longitudinal planes of lateral-medial and antero-posterior mitral annulus were identified on mid-diastolic frame by guidance of short axis image, and lateral-medial diameter (LMD-mpr) and antero-posterior diameter (APD-mpr) were measured in those longitudinal planes (**Figure 1B**).

Post-intervention TTE was performed at an average of 1 day after PMBC. Patients were categorized into three groups based on the PMV results. Considering previous studies demonstrating that clinical outcomes were better when the post-procedural mitral valve area (MVA) was more than 1.75-1.8, ¹⁵⁻¹⁸ we classified patients with an MVA of 1.8 or greater without significant MR as Group SU, patients with an MVA of less than 1.8 without significant MR as Group MS, and patients with an MVA of 1.8 or greater but with significant MR as Group MR.

Procedure technique

The PMBC was performed using Inoue balloon technique with transseptal approaches. The size of Inoue balloon was chosen to obtain the value of effective balloon dilating area divided by body surface area (EBDA/BSA) at approximately 4 cm²/m². In patients who had high echo score or small BSA, balloon sizing was adjusted to achieve an EBDA/BSA ratio close to 3.5 cm²/m² at the discretion of the treating physician.

Clinical Outcomes

The primary clinical outcome was a composite of death from any cause, stroke, re-hospitalization for heart failure and mitral valve surgery. The secondary clinical outcomes

included the individual components of the primary composite outcomes. All stroke events were confirmed by trained neurologists or stroke specialists.

Statistical analysis

Continuous variables were compared using Student's *t*-test or Wilcoxon rank-sum test depending on their distribution and are presented as means with standard deviations. Categorical and ordinal variables were compared using χ^2 or Fisher's exact test, as appropriate, and are presented as frequencies and percentages. In order to assess the correlation between patient's height or BSA and the mitral valve annulus diameters, we used the Pearson correlation coefficient.

Linear regression analysis was performed to evaluate the linear relationship between MV annular diameters and inflated balloon size and consequently optimal formula 4 and 5 were derived. The differences between actually inflated balloon size and calculated balloon size obtained from each formula were evaluated using paired *t*-test.

The event-free survival rate was estimated using Kaplan–Meier analysis, and the difference was compared by log-rank tests. All reported *P* values are two-sided, and *P* values <0.05 were considered to indicate statistical significance. All statistical analyses were performed using R software version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria; www.r-project.org)

Result

Baseline patient characteristics

In a total of 184 patients, seven patients who exhibited both a small MVA and significant MR after PMBC were excluded from the analysis, and consequently 110, 50, and 17 patients were categorized as Group SU, Group MS, and Group MR, respectively (**Figure 2**).

The baseline patient characteristics are summarized in **Table 1**. The mean age of the total patients was 61.0 ± 11.3 years, and 161 (87.5%) were female. There were no significant differences in the distribution of clinical data such as age, sex, height, and weight among the three groups, except for BSA which was relatively large in Group MR, while small in Group MS.

Regarding baseline echocardiographic finding, mean MVA before procedure in overall population was 1.07 ± 0.21 cm² with a mean pressure gradient of 12.0 ± 5.6 mmHg, and a mean echo score of 8.5 ± 1.2 . In Group SU, patients had a larger MVA and lower mean PG, as well as a lower tricuspid regurgitation peak velocity, in comparison to the other two groups. In terms of baseline 3D TEE parameters of mitral annulus, there were no significant differences among the three groups.

Relationship between patient's height or BSA and the mitral annulus diameters

We analyzed the relationship between the patient's height or BSA and the mitral annulus diameters in overall study population. We found the correlations between the patient's height or BSA and LMD-3d were only weak or modest. ($r=0.40$ between height and LMD-3d, $r=0.35$ between BSA and LMD-3d, **Figure 3**). Furthermore, correlations between LMD-mpr and patient's height or BSA were not also strong ($r=0.38$ between height and LMD-mpr, $r=0.28$ between BSA and LMD-mpr).

Formula to determine the Inoue balloon size

We compared three conventional formulas (Formula 1,2,3) for balloon sizing based on the patient's height or BSA with two new formulas (Formula 4 and 5) derived using mitral valve geometry obtained from 3D TEE. Formula 1 is a conventional formula using patient's height; $0.1 \times \text{height} + 10$. Formula 2 and 3 were conventional formulas for determining balloon size based on the patient's BSA. Formula 2 was calculated to adjust the value of EBDA/BSA

at approximately $4 \text{ cm}^2/\text{m}^2$, while formula 3 was of EBDA/BSA at $3.5 \text{ cm}^2/\text{m}^2$. Formula 4 and Formula 5 were derived using linear regression analysis on MV annulus diameter based on 3D TEE data using only Group SU; $0.0684 \times \text{LMD}-3d + 24.309$ (Formula 4) and $0.061 \times \text{LMD}-\text{mpr} + 24.573$ (Formula 5).

Actually inflated balloon size and calculated balloon size from each formula were summarized in **Table 2**. Mean actual size of inflated balloon was 26.72 ± 1.37 mm in overall population. The actually inflated balloon sizes were significantly smaller than the calculated balloon sizes obtained from formula 4 in Group MS (-0.78 ± 1.02 ; $p < 0.001$), while those were significantly larger in Group MR (0.56 ± 1.05 ; $p = 0.04$). In Group SU, there was no significant difference. The actually inflated balloon sizes were also significantly smaller than the calculated balloon sizes obtained from formula 5 in Group MS (-0.81 ± 1.03 ; $p < 0.001$), while those were tended to be larger in Group MR (0.51 ± 1.12 ; $p = 0.08$) (**Figure 4**).

The balloon sizes calculated using formula 1 were significantly smaller compared with the inflated balloon size in all three groups. In contrast, the balloon sizes calculated using formula 2 were significantly larger than the inflated balloon size in all three groups. The balloon sizes calculated using formula 3 were smaller than the inflated balloon sized in patients whose results were successful (Group SU) (**Figure 4**).

In the comparison of calculated balloon sizes between the conventional formulas and the two new formulas, significant differences were found both in the overall population and only in Group SU (**Table 3 and 4**). However, there was no significant difference in the calculated balloon sizes between formula 4 and formula 5 in the overall cohort as well as in Group SU.

Clinical outcomes

The median clinical follow-up period was 3.8 years (interquartile range: 1.9-5.6 years). The event rates of all the clinical outcomes are shown in **Table 5**, and the Kaplan-Meier

curves for primary composite outcomes are presented in **Figure 5**. Group SU had significantly lower incidence of the primary composite outcomes (hazard ratio (HR), 1.83, 95% confidence interval (CI), 0.71-4.72, $P < 0.001$) compared to the other groups. Regarding secondary clinical outcomes, Group SU also showed a significantly lower incidence in all-cause mortality ($P < 0.001$) and re-hospitalization for heart failure ($P < 0.001$), while there were no significant differences among the groups in stroke ($P = 0.598$) or mitral valve surgery ($P = 0.269$).

Discussion

In this study, we evaluated the clinical value of balloon size selection based on the quantitative analysis of MV geometry determined by 3D TEE. The main findings of this study can be summarized as follows; First, we developed two new formulas (formulas 4 and 5) using data of Group SU, based on the mitral annulus diameter obtained from 3D TEE images for determining the optimal balloon inflation size. Second, the calculated balloon size using the new formula 4 was significantly larger in Group MS, while significantly smaller in Group MR than the inflated balloon size. Similar pattern was also observed in formula 5. Third, the calculated balloon size derived from formula 5 did not show a significant difference compared to formula 4. Finally, the primary composite outcomes (all-cause death, re-hospitalization for heart failure, stroke, and mitral valve surgery) were significantly lower in Group SU compared to the other groups.

In the PMBC procedure, conventional balloon sizing based on the patient's height and BSA has long been used.^{9,19,20} However, this method is not anatomy-based, therefore has inherent limitations. In this study, we found that the correlations between annulus diameters and the patient's height or BSA were only weak or modest. Especially, BSA showed weaker correlations, and it is conceivable that annulus diameters do not change according to the patient's body weight change. There have been several studies which demonstrated anatomy-based determination of balloon size using annulus size measurement using 2D TTE, and these

studies showed this method was more effective in resolving a stenotic mitral orifice without resulting in significant iatrogenic MR compared to conventional approach determining balloon size based on the patients' height as a reference.¹¹⁻¹³ However, the mitral valve annulus is a noncircular and nonplanar structure, and there are limitations to measuring mitral annular diameter with 2D TTE. Before PMBC, TEE is a routine examination to exclude presence of thrombus, and therefore 3D TEE can be easily used in clinical practice to measure mitral annulus diameters. 3D TEE can reveal entire anatomy of mitral annulus as well as mitral valve, and dedicated software for mitral valve geometry or MPR images can be used to measure annulus diameters. In this study, we suggested that determining appropriate Inoue balloon inflation size using lateral-medial diameter (LMD-3d and LMD-mpr) might be a reasonable method.

One of the common and important complications after PMBC is significant MR, accounting for 4-18 % in previous studies.^{18,21,22} Therefore, It is important to split the commissures of a stenosed MV without making significant MR. We found that the calculated balloon size using the formula 4 was significantly larger in Group MS, while significantly smaller in Group MR than the inflated balloon size. On the other hand, other formulas did not show this pattern. The formula 1 based on the patient's height generally suggested small size which was also significantly smaller than actual inflated balloon size even in Group SU. Regarding formulas based on BSA, formula 2 suggested too large size while formula 3 suggested too small size compared to the inflated balloon size in Group SU. Therefore, our study shows a possibility that the new formulas based on 3D TEE measurements of the mitral annulus diameter might be a better method to relieve MV stenosis effectively without resulting in significant MR.

Successful PMBC results have clinical implications. In this study, it was found that clinical outcomes in Group SU were better than the other groups. Previous studies have demonstrated that patients with an MVA of 1.75 to 1.8 or lower after the procedure, or those

with significant MR, had worse long-term outcomes.¹⁵⁻¹⁸ Our study result was compatible with those previous studies. These results imply that obtaining an appropriate MVA without making significant MR during PMBC is crucial. Therefore, ensuring successful PMBC outcomes by appropriately sizing the balloon during PMBC is essential.

Our study has several limitations. First, the retrospective single-center design of the study is subject to inherent limitations. There is a possibility that various confounding variables may have influenced on the clinical outcomes. Second, PMBC results might have been affected by various factors other than inflated balloon size, such as pre-procedural MVA and echo score. MVA before PMBC was relatively large in Group SU compared to other groups. However, echo score was not significantly different among groups. Third, the geometric analysis of MV was conducted at mid-diastole in this study, because MVA is measured during diastole. However, mitral annulus size slightly changes even during diastole, and therefore low frame rate of 3D TEE might be a source of individual differences in measurement times in cardiac cycle, especially in patients with atrial fibrillation with rapid ventricular response. Lastly, these new formulas were not validated in a different population. This study is a hypothesis generating study suggesting new formulas of inflation balloon size in PMBC. Further prospective studies are necessary to validate clinical values of these new formulas derived from this study.

Conclusions

Selecting the Inoue balloon inflation size based on the mitral annulus diameter determined by 3D TEE might be a reasonable approach. Further prospective study is warranted to validate the clinical benefit of the formulas derived from this study.

Table 1. Baseline characteristics and echocardiographic parameters of the study population

Characteristics	Overall (N = 184)	Groups stratified by PMBC results			p-value ^f
		Group MS (N=50)	Group SU (N=110)	Group MR (N=17)	
Clinical data					
Age	61.0 ± 11.3	62.8 ± 12.0	60.4 ± 10.6	60.5 ± 11.8	0.49
Gender, n (%)					0.22
female	161 (87.5%)	47 (94.0%)	93 (84.5%)	14 (82.4%)	
male	23 (12.5%)	14 (82.4%)	17(15.5%)	3 (17.6%)	
Height (cm)	157.5 ± 7.4	155.6 ± 7.0	158.2 ± 7.5	158.5 ± 6.4	0.35
Weight (kg)	57.2 ± 9.7	54.1 ± 9.4	58.4 ± 9.9	59.8 ± 7.4	0.36
Body surface area (m ²)	1.58 ± 0.16	1.53 ± 0.15	1.59 ± 0.16	1.62 ± 0.14	0.03
History of atrial fibrillation	88 (47.8%)	25 (50.0%)	53 (48.2%)	7 (41.2%)	0.93
Echocardiography finding					
Mitral valve area by 2D planimetry (cm ²)	1.07 ± 0.21	0.96 ± 0.17	1.13 ± 0.20	1.04 ± 0.17	<0.001
mean mitral valve pressure gradient (mmHg)	12.0 ± 5.6	12.8 ± 5.5	11.0 ± 4.5	13.5 ± 7.8	0.01
Left atrial diameter(mm)	50.5 ± 7.0	49.8 ± 6.9	50.8 ± 7.0	50.4 ± 4.8	0.52
Mitral Regurgitation grade					0.28
None	22 (12.0%)	5 (10.0%)	13 (11.8%)	3 (17.6%)	
Trivial	71 (38.6%)	23 (46.0%)	41 (37.3%)	5(29.4%)	
Mild	85 (46.2%)	20 (40.0 %)	55 (49.9%)	8 (47.0%)	
Mild to moderate	6 (3.2%)	2 (4.0%)	1 (0.9%)	1 (5.9%)	
Tricuspid regurgitation grade					0.69
Mild	151 (82.0%)	37 (74.0%)	94 (85.4%)	16(94.1%)	

Moderate	21 (11.4%)	9 (18.0%)	11 (10.0%)	1(5.9%)	
Severe	12 (6.5%)	4 (8.0%)	5 (4.5%)	0(0%)	
Tricuspid regurgitation peak velocity, m/s	2.9 ± 0.4	3.0 ± 0.4	2.8 ± 0.4	3.0 ± 0.6	0.003
Echo Score	8.5 ± 1.2	8.9 ± 0.9	8.4 ± 1.3	8.4 ± 1.3	0.18
Baseline 3D TEE parameters of mitral annulus					
Annulus area (2D) (cm ²)	11.2 ± 2.8	11.1 ± 2.6	11.3 ± 2.9	11.0 ± 2.7	0.63
Annulus area (3D) (cm ²)	11.8 ± 3.9	11.5 ± 2.7	12.0 ± 4.4	11.4 ± 2.8	0.40
Annulus Height (cm)	0.9 ± 0.3	0.8 ± 0.3	0.9 ± 0.3	0.8 ± 0.2	0.41
Mitral Annulus lateral-medial diameter (LMD-3d) (mm)	37.6 ± 5.1	37.2 ± 4.7	38.0 ± 5.3	37.2 ± 4.8	0.61
Mitral Annulus antero-posterior diameter (APD-3d) (mm)	37.6 ± 5.3	38.0 ± 4.6	37.4 ± 5.2	37.1 ± 6.3	0.74
Lateral-medial diameter on MPR image (LMD-mpr)(mm)	38.0 ± 6.0	37.8 ± 5.7	38.0 ± 6.0	38.2 ± 6.9	0.97
Antero-posterior diameter on MPR image (APD-mpr) (mm)	34.6 ± 5.6	34.3 ± 5.3	34.6 ± 5.5	35.7 ± 6.8	0.63

[†] Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test.

MPR = multiplanar reconstruction, PMBC = percutaneous mitral balloon commissurotomy.

Table 2. Inflated and calculated balloon sizes in the study population

	Overall (N = 177)	Groups stratified by PMBC results		
		Group MS (N=50)	Group SU (N=110)	Group MR (N=17)
Inflated balloon size	26.72±1.37	26.07±1.11	26.91±1.41	27.41±1.06
Formula 1 (Height)	25.75±0.74	25.56±0.70	25.82±0.75	25.85±0.64
Diff-Formula 1 (Inflated – calculated balloon size)	0.97±1.17	0.51±1.01*	1.09±1.19*	1.56±1.06*
Formula 2 (BSA, EBDA=4*BSA)	28.26±1.36	27.78±1.33	28.43±1.37	28.62±1.05
Diff-Formula 2 (Inflated – calculated balloon size)	-1.54±1.17	-1.71±1.12*	-1.52±1.22*	-1.21±0.88*
Formula 3 (BSA, EBDA=3.5*BSA)	26.44±1.27	25.99±1.24	26.59±1.28	26.77±0.99
Diff-Formula 3 (Inflated – calculated balloon size)	0.28±1.13	0.08±1.07*	0.32±1.19*	0.64±0.85*
Formula 4 (LMD-3d)	26.89±0.36	26.85±0.32	26.91±0.37	26.85±0.33
Diff-Formula 4 (Inflated – calculated balloon size)	-0.17±1.31	-0.78±1.02*	0.00±1.36	0.56±1.05*
Formula 5 (LMD-mpr)	26.89±0.36	26.88±0.35	26.89±0.37	26.90±0.42
Diff-Formula 5 (Inflated – calculated balloon size)	-0.17±1.32	-0.81±1.03*	0.02±1.36	0.51±1.12

* represents p value <0.05 by the paired t-test

BSA = body surface area, EBDA = effective balloon dilating area, MPR = multiplanar reconstruction, PMBC = percutaneous mitral balloon commissurotomy.

Table 3. Differences between calculated balloon sizes obtained by use of echo formula in whole study population

	Formula 4 (LMD-3d)	Formula 5 (LMD-mpr)
	P value*	P value*
Formula 1 (Height)	<0.001	<0.001
Formula 2 (BSA, EBDA=4*BSA)	<0.001	<0.001
Formula 3 (BSA, EBDA=3.5*BSA)	<0.001	<0.001

*Paired t-test was used.

BSA = body surface area, EBDA = effective balloon dilating area, MPR = multiplanar reconstruction

Table 4. Differences between calculated balloon sizes obtained by use of echo formula in Group SU

	Formula 4 (LMD-3d)	Formula 5 (LMD-mpr)
	P value*	P value*
Formula 1 (Height)	<0.001	<0.001
Formula 2 (BSA, EBDA=4*BSA)	<0.001	<0.001
Formula 3 (BSA, EBDA=3.5*BSA)	0.007	0.01

*Paired t-test was used.

BSA = body surface area, EBDA = effective balloon dilating area, MPR = multiplanar reconstruction

Table 5. Kaplan-Meier estimates of clinical outcomes

Clinical outcomes	Overall (N = 177)	Groups stratified by PMBC results			p-value*
		Group MS (N=50)	Group SU (N=110)	Group MR (N=17)	
Composite clinical events	23 (13.0%)	7 (14.0%)	10 (9.1%)	6 (35.3%)	<0.001
All cause death	4 (2.3%)	2 (4.0%)	0 (0%)	2 (11.8%)	<0.001
Hospitalization for heart failure	7 (4.0%)	4 (8.0%)	0 (0%)	3 (17.6%)	<0.001
Stroke	5 (4.5%)	1 (2.0%)	5 (4.5%)	0 (0%)	0.598
Mitral valve surgery	5(4.5%)	3 (6.0%)	5 (4.5%)	2 (11.8%)	0.269

*Log-rank test was used, Median follow up duration 3.8 years [Interquartile range, 1.9-5.6]

PMBC = percutaneous mitral balloon commissurotomy

Figure 1. Representative examples of mitral annulus geometry analysis using (A) QLab software and (B) multiplanar reconstruction images. Arrows indicate lateral-medial diameter of mitral annulus (LMD-3d) (yellow), antero-posterior diameter of mitral annulus (APD-3d) (white), lateral-medial diameter on MPR (LMD-mpr) (blue), and antero-posterior diameter on MPR (APD-mpr) (red). AV: aortic valve.

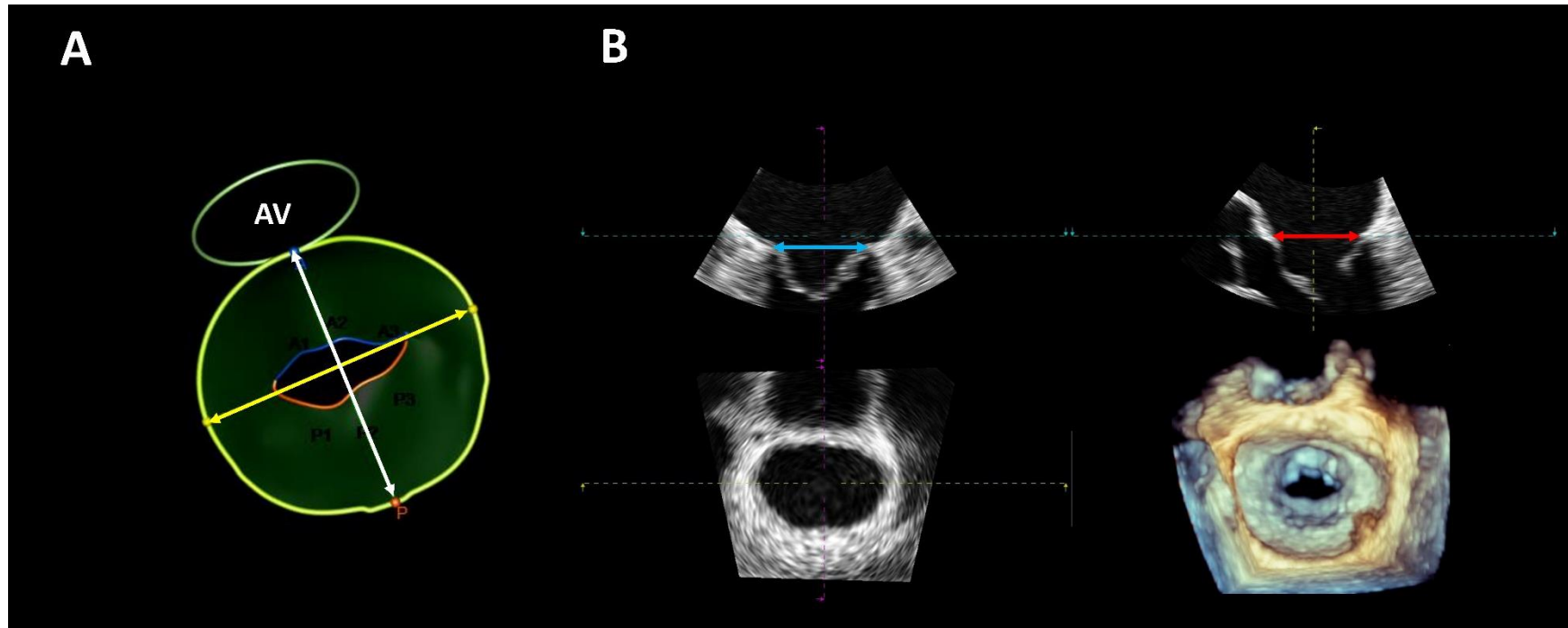


Figure 2. Study flowchart

MR = mitral regurgitation, MS = mitral stenosis, MV = mitral valve, MVA = mitral valve area, PMBC = percutaneous mitral balloon commissurotomy, TEE = transesophageal echocardiography

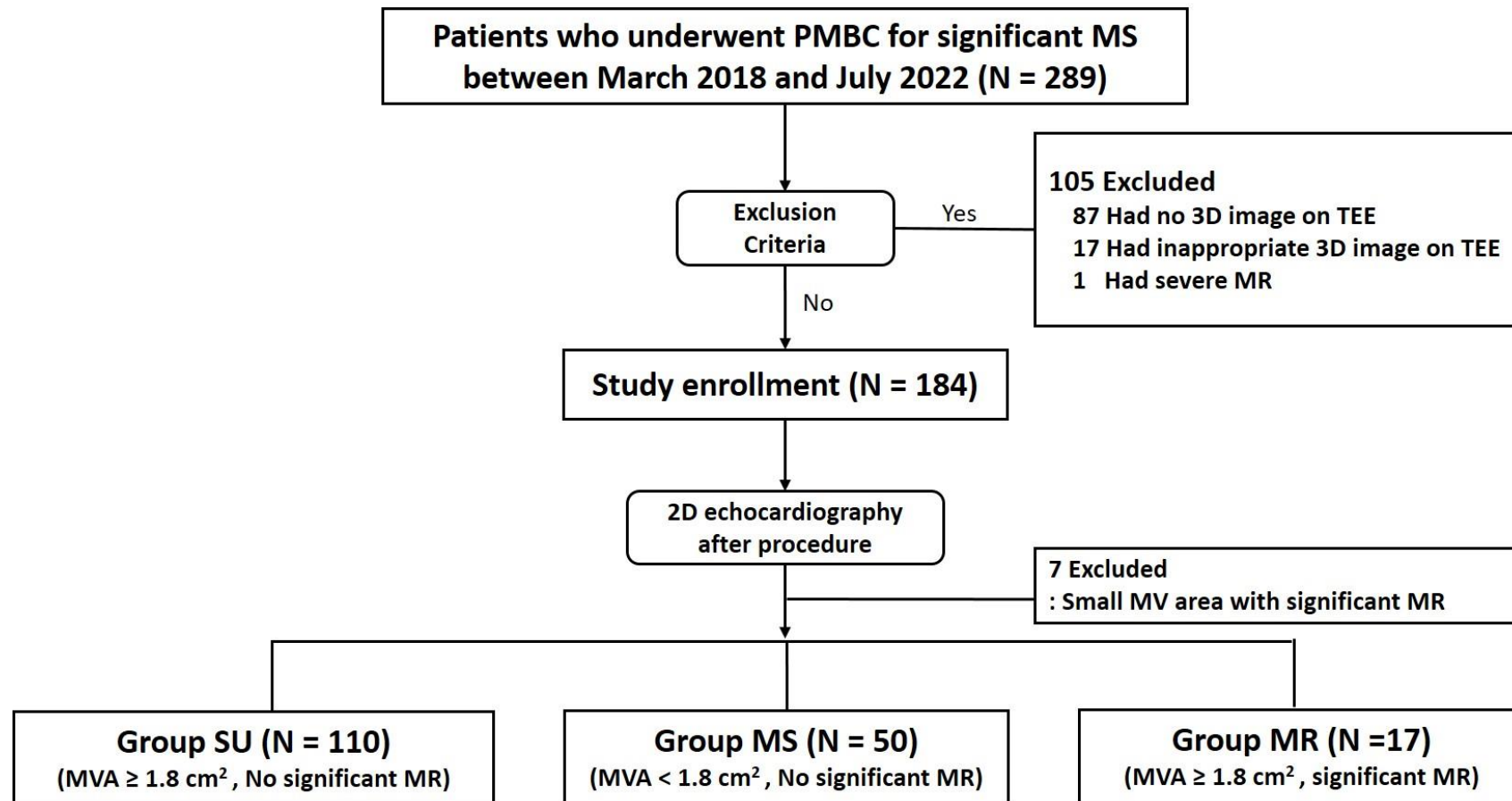


Figure 3. Scatter plots between the patient's height or BSA and lateral medial diameter measured using 3D echocardiography (LMD-3d)

BSA: body surface area, LMD-3d: Mitral annulus lateral-medial diameter

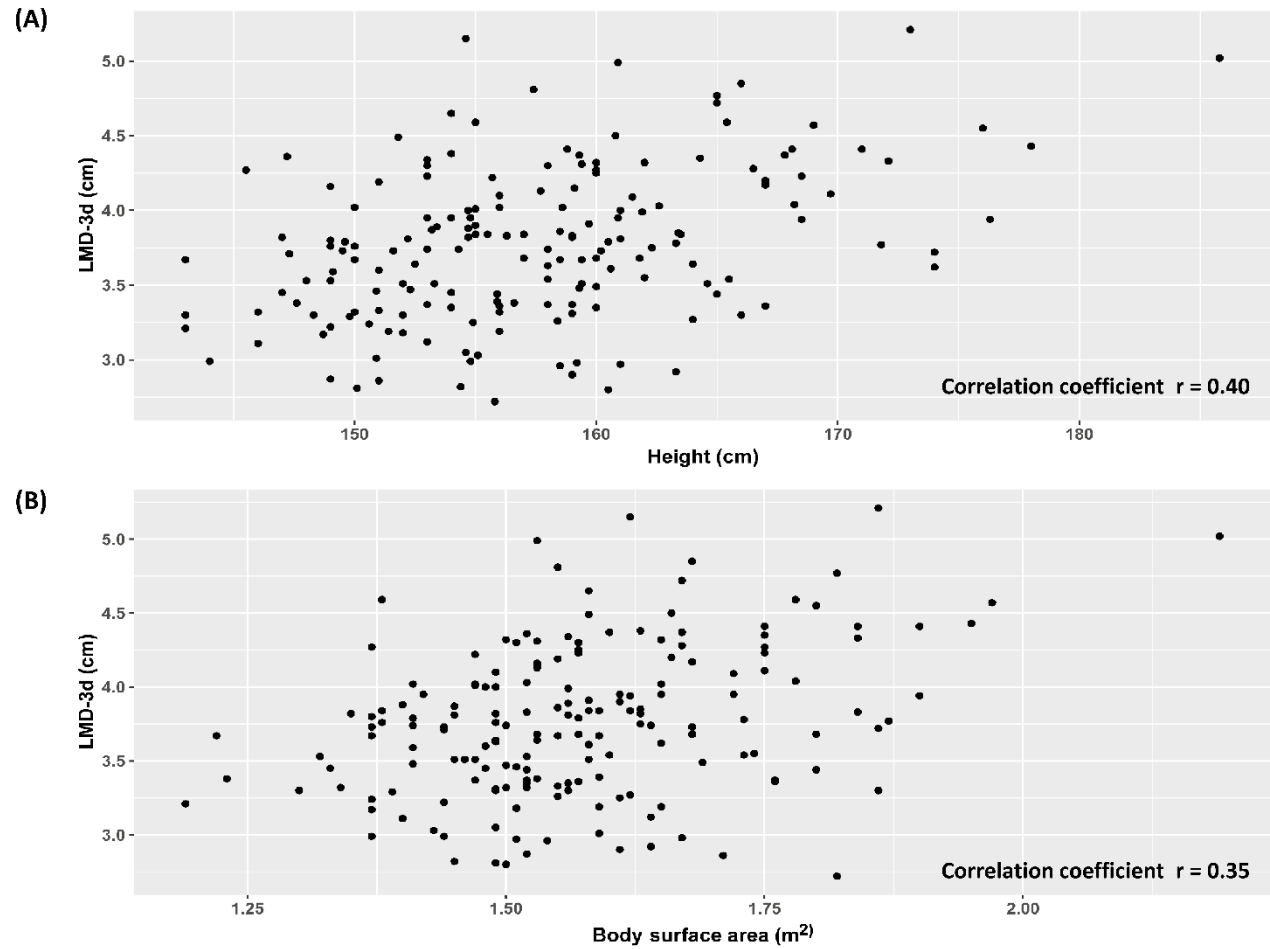


Figure 4. Difference between inflated and calculated balloon sizes determined by various formula in three groups.

* represents p value <0.05 by the paired t-test

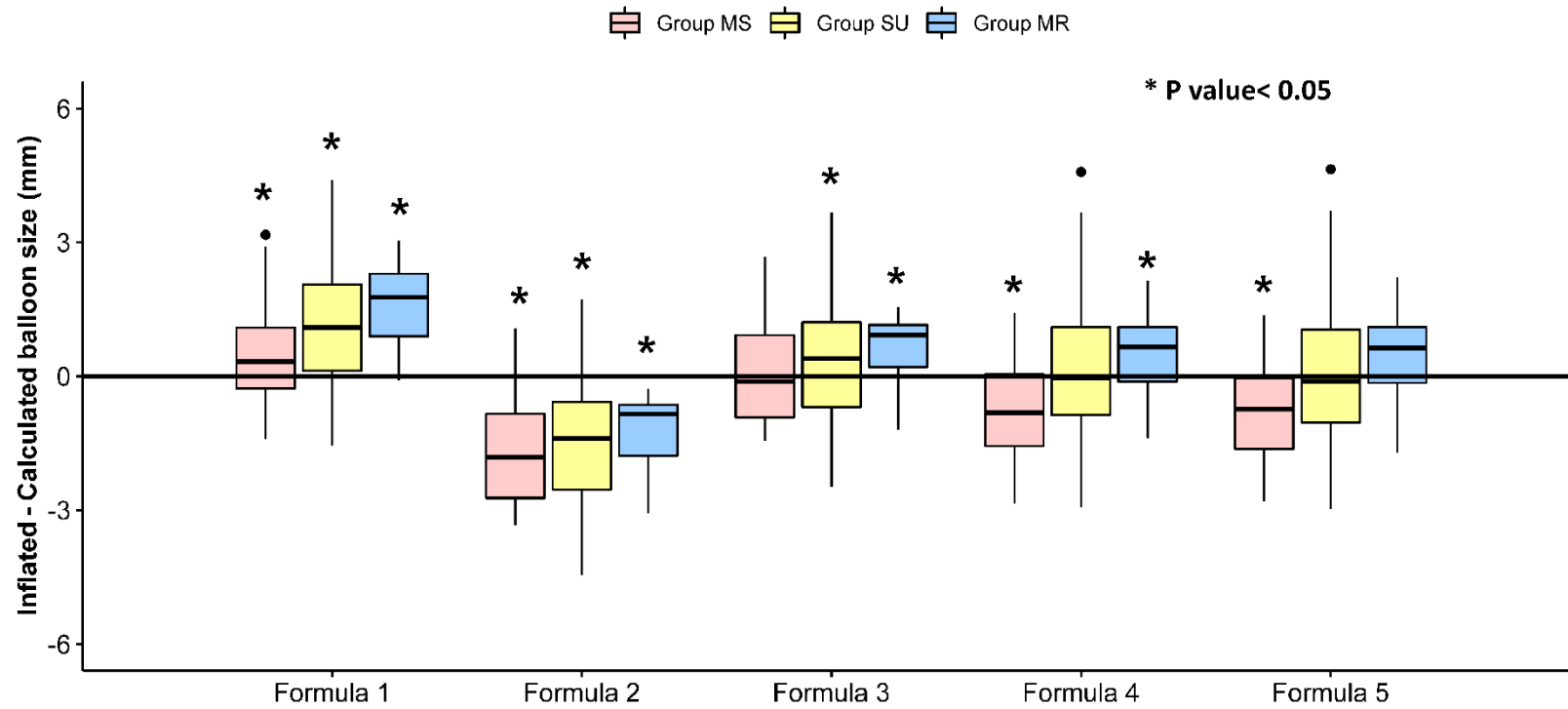
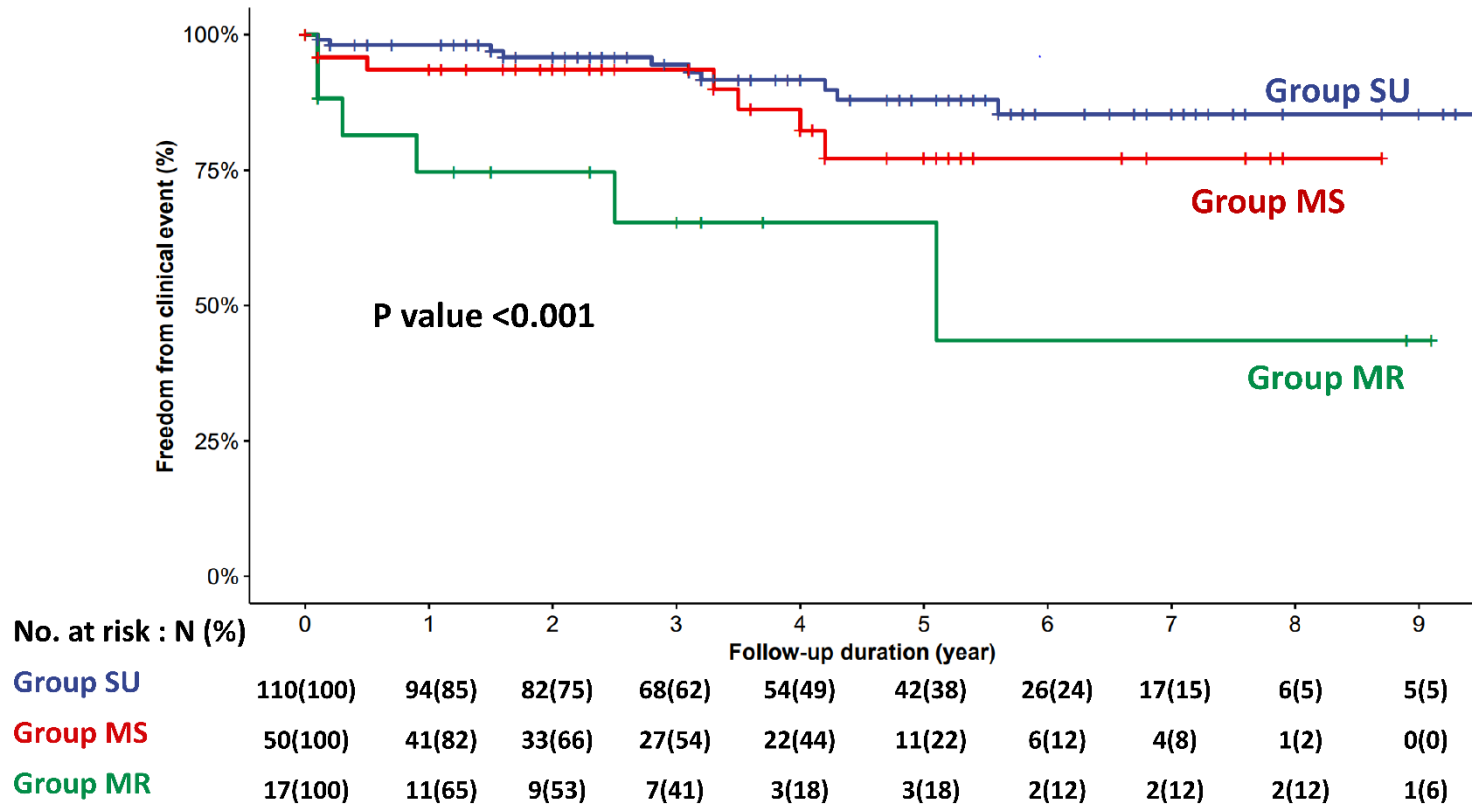


Figure 5. Kaplan-Meier curves of clinical outcomes of three groups



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국문요약

연구 배경: 경피적 승모판 풍선 성형술은 적절한 판막 모양을 가진 승모판 협착증 환자에게서 초기 치료로 권장된다. 적절한 풍선 팽창 사이즈를 결정하는 것은 경피적 승모판 풍선 성형술 시술 시 중요한 단계이다. 본 연구에서는 3차원 경식도 심초음파를 이용한 승모 판막 형상의 정량적인 분석을 기반으로 한 풍선 크기 선택의 임상적 가치를 평가하고자 하였다.

방법: 유의한 승모판 협착으로 경피적 승모판 풍선 성형술을 받은 총 184 명의 환자를 후향적으로 분석하였다. 승모 판막 형상은 mid diastole 때 삼차원 전용 소프트웨어로부터 얻은 Lateral-medial diameter (LMD-3d) 와 multiplanar reconstruction image 로부터 얻은 lateral medial diameter (LMD-mpr) 을 포함하여 분석하였다. 환자들은 경피적 승모판 풍선 성형술의 결과에 따라 1) 성공적으로 결과를 얻은 그룹 (Group SU), 2) 승모판 협착이 남은 그룹 (Group MS) 3), 유의미한 승모판 역류가 생긴 그룹 (Group MR) 세 그룹으로 분류되었다.

결과: Group SU, Group MS 및 Group MR 은 각각 110, 50 및 17 명으로 구성되었다. 우리는 환자의 키 또는 체표면적을 기반으로 풍선 크기를 결정하는 세 가지 전통적인 공식 (Formula 1, 2,3)과, Group SU 의 선형 회귀 분석을 사용하여 승모 판막 형상 분석에서 도출된 두가지 새로운 공식을 비교하였다: 풍선 크기 = $0.0684 \times \text{LMD-3d} + 24.309$ (Formula 4) 및 $0.061 \times \text{LMD-mpr} + 24.573$ (Formula 5). Formula 4 를 사용하여 계산된 풍선 크기와 비교하여 실제로 사용된 풍선의

크기는 Group MS 에서 유의하게 작았으며 (-0.78 ± 1.02 ; $p < 0.001$), 반면 Group MR 에서는 실제로 사용된 풍선의 크기가 유의하게 컸다. (0.56 ± 1.05 ; $p = 0.04$). 이러한 경향은 formula 5 에서도 관찰되었다.

결론: 삼차원 경식도 심초음파를 통해 측정된 mitral annulus 직경에 기반으로 한 이노우에 풍선 사이즈를 결정하는 것은 합리적인 방법이 될 수 있다. 본 연구에서 도출된 공식의 임상적 이점을 검증하기 위해 추가적인 전향적인 연구가 필요하다.

중심 단어: 승모판 협착증, 경피적 승모 판막 성형술, 경식도 심초음파