Complications of Inoue balloon mitral commissurotomy: Impact of operator experience and evolving technique

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Background There have been no single-center studies that have systematically addressed the acute outcome of Inoue balloon mitral commissurotomy (BMC) performed in a large series of patients. Accordingly, this study sought to examine the impact of operator experience and continuing technical modifications on the success and complication rates of BMC.

Methods BMC was performed in 799 patients: 469 patients with pliable mitral valves (group 1) and 330 patients with calcified valves and/or severe subvalvular disease (group 2). Acute complications were examined and compared between groups before and after modifications in BMC techniques. Major modifications included the use of a height-derived balloon sizing method for the selection of an appropriate balloon catheter, a cautionary stepwise dilation technique, and avoidance of traction on the interatrial septum during balloon inflations.

Results Technical failures were encountered in 4 (0.5%) patients in our early experience. One patient sustained cardiac perforation and tamponade and was the only case requiring emergency surgery. There were no deaths. Systemic embolic events were observed in 11 (1.4%), all among the first 353 patients before the routine use of pre-BMC transesophageal echocardiography. Severe postprocedure angiographic (≥3+) mitral regurgitation occurred in 4% of patients, 2% in group 1 versus 9% in group 2 ($P = .0001$). With increased operator experience and technical modifications, this complication was significantly reduced from 5% (7 of 150 patients) to 0% in the last 316 patients in group 1 ($P = .0001$) and from 11% (26 of 228 patients) to 3% (3 of 101 patients) in group 2 ($P = .031$). The incidence of significant interatrial shunting (pulmonary-to-systemic flow ratio ≥1.3) was also significantly reduced from 12% to 6% ($P = .0034$).

Conclusion Incremental operator experience and ongoing technical refinements in BMC techniques have resulted in a 100% technical success rate and a significant diminution in complications in patients with a wide spectrum of stenotic mitral valve morphologic features. (Am Heart J 1999;138:114-21.)

Since the introduction in 1984 by Inoue et al[1] of balloon mitral commissurotomy (BMC) with size-adjustable, self-positioning balloon catheters, various other techniques with fixed-sized balloon catheters have been developed for performing the procedure. These include the antegrade approaches with 1 or 2 balloon catheters through 1 or 2 interatrial septal punctures[2-5] or the retrograde approaches with transseptal wiring or without transseptal access.[6,7] Regardless of the procedure, past observational[4,5,8-17] and randomized[18-22] studies in selected patients with mitral stenosis have demonstrated that BMC affords excellent short- and mid-term outcomes comparable with or even better than those of surgical commissurotomy.

However, as with any interventional procedure, including BMC, there is a learning curve to be surmounted before technical competence is attained. Given this, it is not surprising that different centers with varying levels of technical expertise have yielded different BMC outcomes. In contrast to the low risk profile in skilled centers, unacceptably high incidences of complications have been recorded at institutions with low BMC workload and limited operator experience.[14,23,24] Furthermore, insofar as most data on acute complications have been largely derived from multicenter, cooperative studies[5,23,25,26] with wide variations in outcomes, they are not a true reflection of what can be achieved with BMC when performed by experienced, high-volume operators in one center. Moreover, there have been no reports that have examined the impact of evolving technical strategies on the acute outcome of BMC in a system-

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Table I. Baseline characteristics

Parameters	Total group (n = 799)	Group 1 (n = 469)	Group 2 (n = 330)	*P* value
Age (yr)	45 ± 12	42 ± 12	49 ± 12	.0001
Female	595 (75)	369 (79)	226 (69)	.0011
Atrial fibrillation	491 (61)	257 (55)	234 (71)	<.0001
Embolic history	124 (16)	62 (13)	62 (19)	NS
Left atrial size (mm)*	50 ± 10	49 ± 9	53 ± 11	.0024
Giant left atrium (≥70 mm)	41 (5)	16 (3)	27 (8)	.0033
CT ratio	0.62 ± 0.08	0.60 ± 0.08	0.65 ± 0.08	.0002
MR				
Grade 0	514 (65)	340 (73)	174 (53)	.0001
Grade 1	213 (27)	97 (21)	116 (35)	<.0001
Grade 2	67 (8)	30 (6)	37 (11)	.0156
Grade 1 and 2	280 (35)	127 (27)	153 (46)	<.0001

Data presented are mean ± SD or number (%).
*Measured by M-mode echocardiography.
CT, Cardiothoracic; *NS,* not significant.

atic fashion. Accordingly, the aims of this study were to (1) report the acute complications in a large group of consecutive patients (n = 799) undergoing Inoue BMC at a single center, and (2) examine the impact of operator experience and evolving modifications in technical strategies for BMC with the intent to minimize the acute complications of this procedure.

Methods

Patients

From 1987 to 1996, 799 patients (595 women and 204 men; mean age 45 ± 12 years; range 16 to 84 years) with symptomatic moderate to severe rheumatic mitral stenosis underwent elective BMC. The patients were arbitrarily categorized into 2 groups based on mitral valve characteristics. They were 469 patients with pliable, noncalcified valves (group 1) and 330 patients with calcified mitral valves (detected by fluoroscopy) and/or severe subvalvular lesions (group 2). Severe subvalvular lesions are defined as severe thickening and shortening of the chordal structures determined echocardiographically or fluoroscopic evidence of compression of the inflated Inoue balloon.[9] The baseline characteristics of group 1 and 2 patients are shown in Table I. High-risk comorbid conditions were present in 40 patients: major pulmonary diseases in 21 (chronic obstructive lung disease in 20 and pneumoconiosis in 1), severe kyphoscoliosis in 4, uremia in 4, systemic lupus erythematosus in 2, chronic liver cirrhosis in 1, hyperthyroidism in 3, hyperparathyroidism in 1, multiple myeloma in 1, and pregnancy in 3 (5 to 7 months' gestation). Twenty patients had mitral restenosis after previous open surgical commissurotomy, and 2 patients had associated atrial septal aneurysm.[27,28]

After the first 50 group 1 patients, the inclusion criteria were subsequently broadened to include group 2 patients.[9] The only 2 absolute contraindications for BMC are the presence of severe mitral regurgitation (MR) (≥3+ by Sellers' angiographic criteria[29]) and left atrial cavity thrombus identified by echocardiography. However, those with left atrial thrombus confined to the appendage area were not excluded.[30] In 46 patients, BMC was performed after resolution of the left atrial cavity thrombus. The thrombus resolution was found incidentally in 2 patients[31] and after 3 to 12 months of warfarin treatment in the other 44 in an ongoing prospective study of thrombus resolution.[32] Since 1990, when transesophageal echocardiography became a routine procedure performed 1 or 2 days before BMC, thrombi confined to the left atrial appendage were demonstrated by transesophageal echocardiography in 95 patients (1 with sinus rhythm and 94 with atrial fibrillation: 93 chronic and 1 paroxysmal). These included 17 patients who had left atrial cavity thrombi resolved after warfarin therapy. All patients underwent a comprehensive 2-dimensional and Doppler echocardiographic study before and on the day after BMC.

BMC protocol

After obtaining informed consent, a one-stage diagnostic and interventional procedure was performed as previously described,[9,15,33,34] primarily by one of the authors (J.S.H.); other authors were either secondary operators or performed the procedure under supervision. In brief, transseptal access designed for Inoue BMC was performed without routine right atrial angiography.[33] The latter was used to guide the transseptal puncture during our learning phase (n = 15) but later used only in patients at high-risk of cardiac perforation (n = 12: 4 with severe kyphoscoliosis, 7 with giant left atria, and 1 with a large interatrial septal aneurysm). Subsequently, intracardiac ultrasound was used in place of angiography in 12 other patients with high-risk settings to examine its clinical use in securing a safe and optimal transseptal catheterization.[28]

BMC was performed with the stepwise dilation technique. After each balloon dilation, the left atrial pressure, left ventricular pressure, and the mitral valve gradient were assessed. BMC was terminated once a satisfactory hemodynamic outcome was obtained, when the transmitral gradient failed to decrease further despite 2 to 3 more inflations with larger balloon sizes, or when significant MR was suspected. Such suspicion was based on observation of accentuated left atrial v waves with lack of reduction or increase in the mean left atrial pressure and on auscultation after each valve dilation. MR was confirmed, if necessary, by intraprocedural echocardiography

or left ventriculography. After withdrawal of the balloon catheter, an oximetry series was performed.

Evolving balloon sizing approach

Our balloon sizing method evolved in 3 phases. In the initial phase (n = 163), the balloon size was based on patient body surface area,[35] as originally described by Inoue. The second phase (n = 380) began after an empirical formula based on height was derived to determine the reference balloon size (RBS).[9] This approach estimates RBS, guides the selection of an appropriate balloon catheter that is nominally equal to or encompassing the RBS, and serves as a guide to determine balloon size for the first inflation.[13]

The final modifications in balloon sizing (n = 256) were derived from the following observations. In multivariate analyses,[9,13] independent predictors for severe MR were balloon oversizing (beyond the RBS) in group 1 and preexisting MR and severe subvalvular disease in group 2. Moreover, in the latter group, severe MR could occur at any balloon size. The above collective strategic changes cumulated in the controlled stepwise dilation technique,[34] which consists of (1) initial balloon sizing: RBS – 2 mm in group 1 and RBS – 4 mm in group 2 patients; (2) balloon size increments: by 1 mm in both low- and high-pressure zones in low-risk patients and by 0.5 mm in the high-pressure zone in high-risk scenarios (preexisting MR or any suggestion of an increase in MR and severe subvalvular disease). The high-pressure zone refers to the 2-mm range below an individual catheter balloon's nominal diameter (eg, 24 to 26 mm in a PTMC-26 catheter [Toray Medical, Toyko]) within which intraballoon pressure precipitously increases as the balloon diameter is increased from the low-pressure zone[13]; and (3) balloon catheter downsizing: switching to a catheter 1 size less than the RBS-matched size in the presence of the balloon "impasse." This rare sign indicates that the catheter balloon, though deflated and properly aligned with the mitral orifice/apical axis, has been checked at the subvalvular lesion.[36] However, regardless of valve morphologic features, the initial balloon inflation is never performed within the high-pressure zone.

Statistical analysis

Data are presented as mean ± SD. Comparisons between continuous and categoric values before and after BMC were analyzed by Student *t* test and chi-square test, respectively. Univariate and multivariate analyses (with a model of stepwise logistic regression) were performed to determine the predictors of significant post-BMC MR. Twenty-two variables were analyzed: 7 baseline clinical (age, sex, weight, height, body surface area, presence of atrial fibrillation, and preexisting MR), 6 echocardiographic (left atrial dimension, leaflet mobility, thickening, calcification, severity of subvalvular disease, and total echocardiography score), 6 hemodynamic (left atrial, right atrial and pulmonary artery pressures, mitral valvular gradient, mitral valve area, and cardiac output), and 3 procedure-related (final balloon size, number of inflations, and difference between the final balloon size and RBS). The risk predictors of significant post-BMC interatrial shunting (defined as a pulmonary-to-systemic flow ratio ≥1.3 by oximetry), including the above 22 variables and interatrial septal resistance, were also analyzed. Septal resistance was graded semiquantitatively according to the resistance encountered during transseptal puncture with the Brockenbrough needle: grade 1, little or no septal resistance; grade 2, slight to moderate resistance; and grade 3, marked resistance with "tenting" and "staining" of the septum during test injection of contrast.[35] Statistical analyses were performed with a standard statistical package (StatView for Macintosh, Abacus Concepts, Inc, Berkeley, Calif). A P value <.05 was considered significant.

Results

Technical success, defined as completion of transseptal access and mitral valve dilation, was achieved in all except 4 patients (99.5%). Three of the 4 failures occurred among the first 15 patients: 2 from an inability to cross the mitral valve; 1 from a structural flaw of a prototype Inoue balloon resulting in deflation failure[9]; and 1 a result of inadvertent biatrial perforation with resultant cardiac tamponade in a patient with giant left atrium.[33] Various complications are shown in Figures 1 and 2.

Clinical success, defined as technical success in the absence of an in-hospital adverse cardiovascular event (death, emergency surgery, severe MR, embolism) was achieved in 760 (95%) of 799 patients: 459 (98%) of 469 group 1 patients versus 301 (91%) of 330 group 2 patients ($P < .0001$). Optimal dilation, defined as final mitral valve area of ≥1.5 cm^2 or a gain of ≥50% of the initial valve area without resultant severe (≥3+) angiographic MR, was obtained in 711 (89%) of 795 patients: 450 (96%) in group 1 versus 261 (79%) in group 2 ($P < .0001$).

Cardiac tamponade, emergency surgery, and death

As already mentioned, cardiac tamponade from cardiac perforation occurred in 1 patient (case 375), who was also the only case who underwent emergency surgery.[33] No patients died as a result of the BMC procedure.

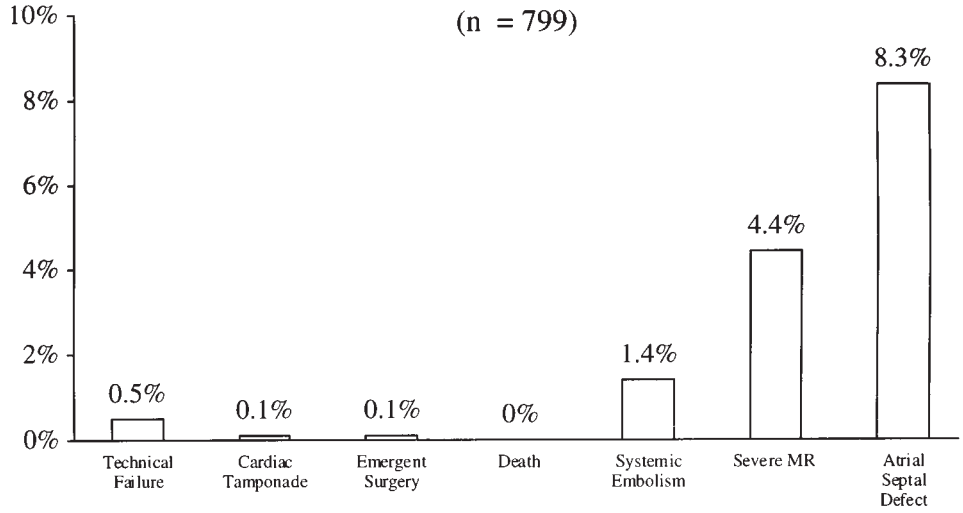
Systemic embolism

Systemic embolic events were observed in 11 patients (1.4%): 9 nonfatal cerebral embolisms (5 strokes and 4 transient ischemic attacks) and 2 peripheral arterial embolisms. All these embolic events occurred among the first 348 patients, before 1990, when preprocedural transesophageal echocardiography to exclude the presence of left atrial cavity thrombi was not routine.

MR

Changes in the degree of MR were assessed by left ventriculography before and after BMC in 780 (456 in group 1 and 324 in group 2) of 795 patients in whom mitral valves were dilated. In the other 15 patients without this angiographic data, color Doppler 2-dimensional echocardiography showed mild increase in the degree of MR in 6 patients and resultant severe MR in none. Angiographic MR was present before BMC in 273 (35%) of the 780 patients: 122 (27%) of 456 group 1 patients versus 151 (47%) of 324 group 2 patients ($P < .0001$). BMC produced an increase in MR in 254 patients (33%): 132

Figure 1



Overall incidences of technical failure and complications of Inoue BMC in 799 patients.

(29%) group 1 patients versus 122 (38%) group 2 patients ($P < .011$). One-grade increase in regurgitation was detected in 188 (24%) patients, 2 grades in 53 (7%), 3 grades in 15 (2%), and 4 grades in 1 patient (0.1%).

Severe MR occurred in 35 (4%) of 795 patients in whom the mitral valve was dilated (Figure 1): 7 (2%) in group 1 patients versus 28 (9%) in group 2 patients ($P < .0001$). Three of the 4 patients with 4+ MR required stabilization with vasodilator therapy and underwent mitral valve replacement 4 to 30 days later. At surgery, severe subvalvular diseases were confirmed in all 3 patients. A severe tear of the anterior mitral leaflet was noted in 2 patients and extensive laceration of the posterior commissure in the other patient. The remaining patient with 4+ MR declined surgery and died 14 months later from intractable heart failure. Nine patients (7 in group 1 and 2 in group 2) had a decrease in MR of 1 grade.

Multivariate analyses revealed that independent predictors for severe MR were balloon oversizing in group 1 and preexisting MR and severe subvalvular disease in group 2. As shown in Figures 2 and 3, the incidence of postprocedure severe MR in group 1 was significantly reduced from 5% to 0% after technical modification in the balloon sizing strategy, namely that of avoiding balloon oversizing. Similarly, the frequency of this complication in group 2 was significantly reduced from 11% to 3%. However, before this reduction there was a surge in the incidence of severe MR to 18% (n = 9) among cases 201 to 250 (Figure 3). This increase was accounted for by the initial 6 patients with the balloon impasse sign.[36] In the subsequent 7 patients with balloon impasse, severe MR was circumvented when catheters smaller than the RBS-matched balloon catheters for initial dilations were selected.

Atrial septal defect

As depicted in Figure 2, the incidence of interatrial shunt was significantly reduced after technical modification to avoid traction on the septum. This was accomplished by releasing the tension exerted on the catheter once the balloon was partially inflated and anchored at the mitral valve.[34] There were no differences between the 2 groups (before and after the modification) with regard to baseline clinical characteristics, valvular morphologic features, and hemodynamic variables. Surgical closure of the defect was required in 1 patient in our early experience.[37]

Univariate analysis identified male sex, atrial fibrillation, the degree of septal resistance, and number of balloon inflations as risk predictors. Among these, septal resistance and number of balloon inflations (>5) emerged as independent predictors in the multivariate model.

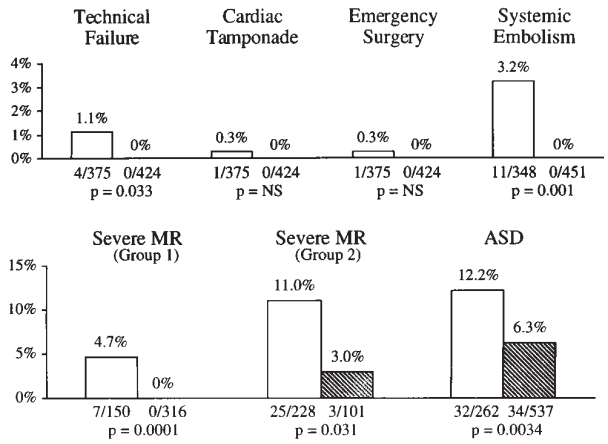
Arrhythmias

Three patients sustained ventricular tachycardia as a result of left ventricular irritation by the pigtail catheter. In one of these patients, tachycardia was resolved by simple withdrawal of the catheter to the aorta, whereas the other 2 patients required cardioversion (intravenous lidocaine in 1 and electrical cardioversion in the other). Paroxysmal atrial fibrillation, which occurred during guide wire or catheter manipulations, was observed in 11 (4%) of 308 patients in sinus rhythm. There were no instances of atrioventricular block during the procedure.

Discussion

This single-center, large-scale study of BMC with the Inoue balloon technique demonstrates the crucial impact

Figure 2



Impact of incremental operator experience and evolving technical refinements on Inoue BMC complications. *Left and right bars*, respectively, show incidence of each category of complications in the first and second series of patients. *ASD*, Atrial septal defect; *NS*, statistically insignificant.

of both operator experience and technical modifications on the success and safety of the procedure. It also highlights the applicability of BMC in a broad spectrum of patients with mitral stenosis, regardless of their clinical characteristics, comorbidities, and valvular morphologic features. The high success rate and decremental frequency of major complications are attributable to our evolving technical modifications targeted at improving our BMC outcome. Among our first 375 cases, there were 4 technical failures and 1 cardiac tamponade resulting in emergency cardiac surgery, but no deaths. In the subsequent 424 patients, the technical success rate was 100% without the occurrence of cardiac tamponade, systemic embolism, emergency cardiac surgery, or death.

Technical failure

The technical failure rates in Inoue BMC have been reported to be 2% to 16%, with most failures occurring in the operator's early experience, either because of failure in transseptal catheterization or unsuccessful balloon crossing of the mitral valve.[14,20] In this study, we have been able to achieve an overall technical success rate of 99.5% despite the presence of a significant number of technically demanding scenarios and high-risk comorbid conditions. The key to the high success rate in this study, we believe, is our continuously evolving Inoue BMC technique.[9,13,33,34,36]

Cardiac tamponade, emergency surgery, and death

Cardiac tamponade in BMC most commonly occurs as a consequence of erroneous transseptal puncture.[14,38-40] Less frequently, it is the result of guide wire– or balloon catheter–induced left ventricular perforation. The latter phenomenon appears to be unique to the fixed balloon catheter technique[14] with a reported incidence of 5% in 1 study.[5] In contrast, left ventricular perforation has not been reported with the Inoue BMC procedures.[37] The cited cardiac tamponade rates in Inoue BMC ranged from 0% to 3%.[14,38] To avert cardiac perforation during transseptal catheterization, many interventionalists have resorted to routine right atrial angiography and others to intraprocedural transesophageal echocardiography to facilitate optimal transseptal needle placement. However, even with the use of intraprocedural transesophageal echocardiography, cardiac perforation may still occur.[39] Therefore ultrasound guidance cannot be relied on entirely: acquisition of basic transseptal skills are essential. The high success rate observed in our study indicates that routine use of these adjunctive maneuvers is unnecessary.

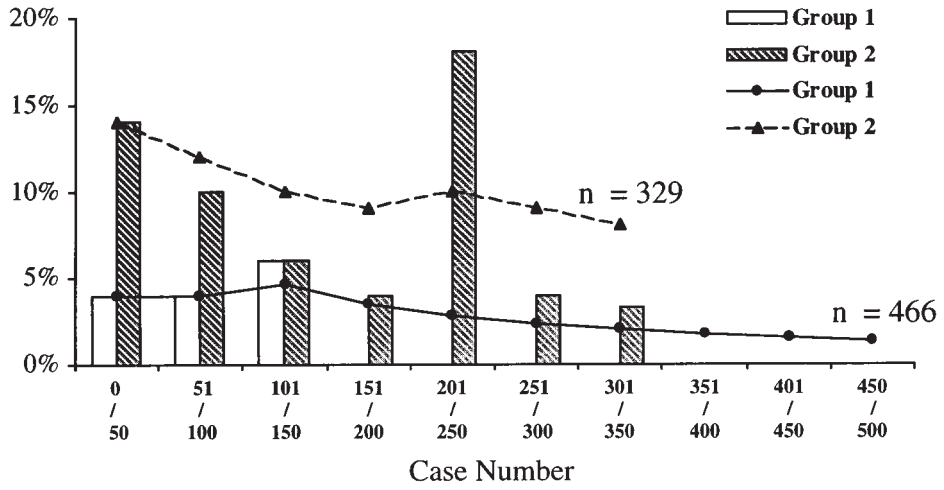
Emergency surgery in BMC is occasionally required because of cardiac tamponade or resultant severe MR.[40] In this study, the only emergency surgery was performed in the patient who had cardiac perforation and tamponade not amenable to pericardiocentesis. Procedure-related deaths resulting from cardiac perforation and tamponade, cerebral embolism, and emergency surgery are known complications of BMC.[14,22] In our series, however, there were no procedure-related deaths.

MR

Several important findings pertaining to procedure-related MR were demonstrated in this study. First, it confirms the fact that mild angiographic MR (1+ to 2+) after BMC is indeed common. The 33% incidence observed in our series of patients is comparable, with the range of 20% to 40% noted in past studies.[14] However, this minor complication, usually the result of commissural oversplitting, is of no clinical relevance.[41] Second, severe MR occurred in 4% of patients; compared with group 1 patients with ideal valves, group 2 patients with unfavorable valve characteristics incurred a significantly higher incidence of severe MR (9% vs 2%). In the latter group, the presence of severe subvalvular disease was identified to be an independent predictor for severe MR, and the creation of severe MR in this group was largely unpredictable and could occur at any balloon size.[9]

Severe MR (≥3+), reported in up to 17% of patients after BMC,[14,41-43] remains a deep-seated concern because it is frequently caused by leaflet tear or, less commonly, chordal rupture and may require urgent mitral surgery. Severe subvalvular disease may predispose to chordal rupture or valve disruption by transmitting balloon pressure in an abnormal and undesirable fashion, thereby causing severe MR after BMC.[42-44] In our study, severe subvalvular disease was observed in all 3 patients with postprocedural severe MR who subsequently underwent surgery. Last but not least, this study has demonstrated

Figure 3



Frequency of severe postprocedure angiographic MR. *Bar graph* indicates incidence of regurgitation at 50-case divisions, and *line graph* shows cumulative incidence of regurgitation.

an approach to reduce the risk of creating severe MR. These various modifications—resulting in a controlled stepwise dilation technique[34]—in our strategy appear to have paid off, as reflected in the reduced incidence of severe MR from 11% to 3% in group 2.

Systemic embolization

Although systemic embolism as a result of air embolization from balloon rupture, fragmentation and embolization of calcified mitral nodules, and in situ thrombus formation on the guide wire or balloon catheter have been sporadically reported,[8,40] the principal causal mechanism of systemic embolism is presumed to be a consequence of left atrial thrombus dislodgment. It is therefore hardly surprising that all 11 BMC-related embolic phenomena in this study occurred before the exclusion of left atrial cavity thrombus by preprocedural transesophageal echocardiography. It is also possible that subtherapeutic systemic anticoagulation during prolonged procedures in our early experience could have contributed to this complication.[9] This study also demonstrates that Inoue BMC, when executed with extra care,[36] is safe in patients with left atrial appendage thrombus.

Atrial septal defect

Although the majority of atrial septal defects are clinically insignificant and spontaneously close within several months after successful BMC,[14] on rare occasions some do become hemodynamically significant and require surgical repair, as illustrated in one of our early cases.[28] The Inoue balloon can be slenderized before its insertion or withdrawal across the septum and may thus inflict less damage to the septum compared with the double-balloon system, which lacks this feature.[14] Significant atrial septal defect after Inoue BMC has been previously reported to occur in approximately 10% to 20% of cases[14]; the 12% incidence in our early experience concurs with this figure.

The risk of creating a significant interatrial shunt logically depends on the stress exerted on the interatrial septum. Our findings that interatrial septal resistance and number of balloon inflations were independent predictors of significant interatrial shunting substantiated this assumption. Septal resistance is an indicator of septal thickness, which in turn determines the propensity to withstand the stress exerted on the transseptal access site. Cognizant of this risk correlation, we altered our technique by simply releasing the traction on the balloon catheter once the balloon was anchored at the mitral valve during each balloon inflation. This technical modification led to a significant decrease in the incidence of interatrial shunting after BMC from 12% to 6%.

Study limitations

There exists a number of limitations in this study. First, because of its design in examining the impact of operator experience and evolution in technique on the acute outcomes of BMC, the present series is an observational study and not a randomized controlled trial, and thus there exist limitations inherent in this type of study. Second, it is possible that there is some operator bias because the results were not blinded. Third, the patients were arbitrarily divided into 2 groups based simply on the presence or absence of fluoroscopic valvular calcification and severe subvalvular lesions

determined by echocardiography or by fluoroscopic balloon compression during inflation. The latter 2 features have previously been demonstrated to be major determinants of BMC outcomes.[14] An echocardiographic scoring system, however, was not used to subdivide patients, primarily because in our experience valve morphologic features based wholly on echocardiographic assessment are not predictive or are at best a weak predictor of BMC outcomes; other investigators have arrived at similar findings.[14] Fourth, this study describes the acute results mainly from a technical standpoint. Although our evolving strategies clearly have a positive impact on the success and complication rates of BMC, whether or not they will afford a marked difference in the long-term follow-up outcome is yet to be determined. Fifth, although it remains speculative, the acute outcome might have improved had intraprocedural echocardiography been performed to examine the amount of commissural splitting and degree of MR after each balloon dilation and to guide the termination of the procedure. And last, given the major differences in the techniques and learning curves of the 2 main BMC approaches (Inoue balloon and double-balloon), the impact of evolving modifications on the acute results in this study concern only Inoue BMC and cannot be extrapolated to the double-balloon approach.

Clinical implications and conclusions

This study demonstrates that operator experience and continuing technical refinements and modifications have a positive and dramatic impact on acute procedural outcomes. Backed by the high technical success rate and decremental risk of acute procedural complications, and given the paucity of data and lack of consensus on the selection criteria for Inoue BMC, we continued to extend the procedural indications to explore the technical limitations of Inoue BMC. As a result, we found that the procedure can indeed be safely performed in a wide spectrum of patients, including those with adverse valvular morphologic characteristics, left atrial appendage thrombus, and various medical comorbidities. The presence of severe (≥3+) MR and left atrial cavity thrombus, however, continue to be absolute contraindications to BMC.

Selection of patients for BMC procedure is a complex decision involving consideration of multiple variables, including clinical profile, valve morphologic characteristics, and operator skill. Although BMC for patients with pliable, noncalcified mitral valves with minimal subvalvular disease and grade 0 or 1+ angiographic MR is proven and well accepted,[18-22] its clinical use in those with less favorable valve anatomy (such as our group 2 patients) is unclear and controversial.[14] This study, however, clearly depicts that even in this subset of patients, Inoue BMC can still yield a low risk of major complications, resultant severe MR in particular, and therefore supports our more liberal use of the procedure. Notwithstanding this finding, it cannot be overemphasized that BMC in these patients can be technically demanding and does require a higher level of technical skill and extra caution in executing the procedure. Furthermore, although limited data[9,13,17,45] appear to indicate that the long-term results of BMC in patients with significant valvular calcification and/or severe subvalvular disease may not be as favorable (higher restenosis rate and a greater need for mitral valve replacement) as in those with optimal valve features, the procedure continues to offer sustained functional benefits in a substantial number of patients with certain characteristics. Future analyses of long-term results are needed to define the indications for Inoue BMC further, especially in this subset of patients with adverse valve morphologic characteristics.

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