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Comparison of Outcome among Double, Bifoil and Inoue Balloon Techniques for Percutaneous Mitral Valvuloplasty in Mitral Stenosis

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The efficacy and complications of three different methods of percutaneous mitral valvuloplasty (PMV) were evaluated in 245 patients with mitral stenosis (MS). Eight six patients (35%) had severe MS defined in the mitral valve area (MVA) $<1.0\ cm^2$ (0.8 ± 0.2) and Echoscore $\geq$ 8(8.9 ± 1.1). The results including post MCA $\geq 1.5cm^2$ and complications, i.e, increment of mitral regurgitation (MR) $\geq +1$ and atrial septal defect (ASD) with Qp/Qs ≥ 1.5 were compared in overall and in severe MS groups. There was no statistically significant difference in size of MVA before and after PMV between overall patients group and severe mitral stenosis group $(0.8\pm0.1$ vs $1.7\pm0.4cm^2$ in the double technique, 0.8 ± 0.2 vs $1.5\pm0.3cm^2$ in the Bifoil technique and 0.7 ± 0.2 vs $1.8\pm0.3cm^2$ in the Inoue techniuqe. p: NS). However, a significantly larger number of patients in the severe MS group had better MVA with the double than the Bifoil techniqe [MVA $\geq$ $1.5cm^2$; 42 (72%) vs 6 (46%), $p<0.005$] whereas higher complications were observed with the Bifoil than the Inoue technique (MR $\geq +1$; 9 (69%) vs 4 (27%), ASD (Qp/Qs $\geq 1.5'$ 6 (46%) vs 2 (13%) $p<0.005$). We conclude that selection of balloon techniuqe for PMV is depend upon the mitral valve pathology. We recommend the double balloon technique for severely thickened valve leaflets and subvalvular structures. The Inoue balloon technique is better for lesser deformed valve leasflets and lower echoscore valves because of its simple technique.

Key Words: Percutaneous mitral valvuloplasty, double, bifoil, Inoue balloon

Since the nonsurgical treatment of mitral stenosis using a single balloon has been introduced by Inoue *et al.* in 1984, percutaneous mitral valvuloplasty (PMV) has become an accepted therapeutic modality for the treatment of selected patients with mitral stenosis (MS). Zeibag *et al.* (1986) demonstrated that the double balloon technique showed a better outcome than the single balloon in obtaining the optimal mitral valve area. On the other hand, there are several reports that single balloon technique was comparable with the double balloon technique (Bassand *et al.* 1990; Herrmann *et al.* 1989; Inoue *et al.* 1989; Kasab *et al.* 1989; Manga *et al.* 1989). Therefore, there are still controversies in efficacy, benefits and complications among balloon techniuqes.

The purpose of this study is to compare the efficacy, complication rate and benefit among the balloon techniques. A retrospective study was performed to compare the outcome of the three different groups by balloon technology used. The double, Bifoil and Inoue balloons were utilized (Fig. 1). The immediate outcome was compared in patients overall and in patients with a severe mitral stenosis which had defined echoscore of 8 or more (Abascall *et al.* 1988) and mitral valve area of less than $1.0\ cm^2$.

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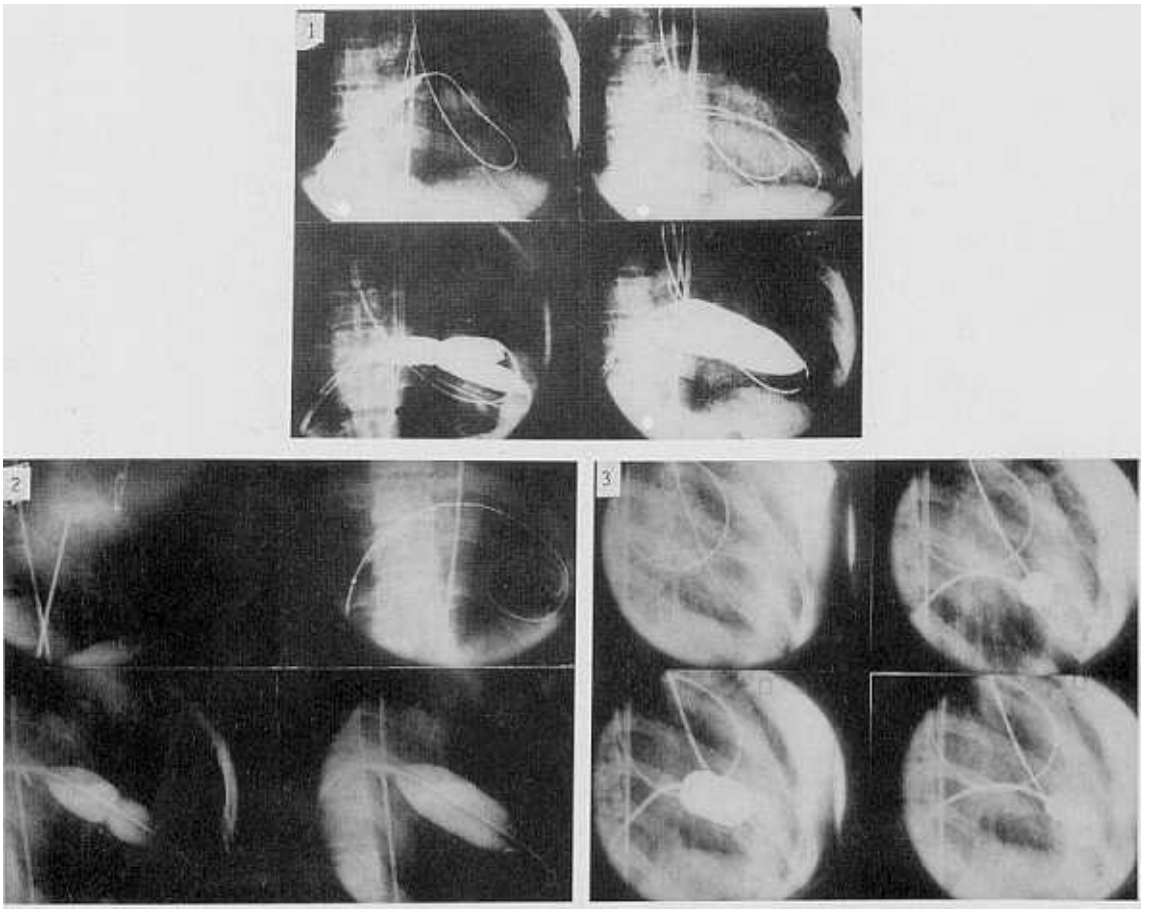

Fig. 1. Three different balloon methods (1. Double, 2. Bifoil, 3. Inoue balloon technology)

MATERIALS AND METHODS

Patient population

PMV was performed in 245 patients by the antegrade transseptal approach in Severance Hospital, Yonsei University College of Medicine during the period from April 1988 to September 1990. Separate double balloons were used in 161 (66%) cases, a Bifoil balloon in 34 (14%) cases, Inoue in 35 (14 %) cases and others (single large Cook balloon and Mansfield balloon) in 15 (6%) cases (Fig. 2). The clinical profiles of the three balloon groups in overall patients and severe stenosis patients are listed in Table 1 and 2.

The clinical profiles include the age, sex, cardiac rhythm, mitral valve area before and after PMV, total echoscore and the ratio of effective balloon di-

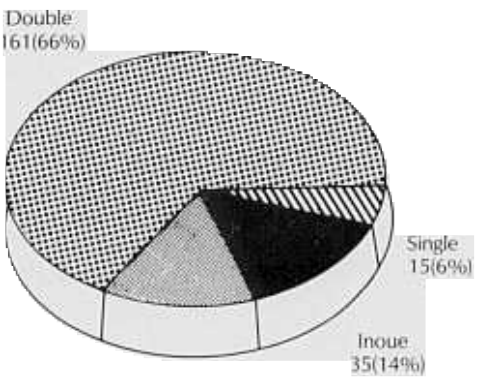

Fig. 2. Kinds of balloon technology used.

Table 1. Clinical profiles of 3 groups in overall patients

	Double (n=161)	Bifoil (n=34)	Inoue (n=35)
Age	40±10	37±10	42±13
Sex	46/115	13/16	10/15
NSR/AF	104/57	23/11	19/16
Pre-MVA	0.9±0.3	0.9±0.2	1.1±0.7
Post-MVA	1.8±0.4	1.8±0.4	1.9±0.6
Echoscore	8.0±1.5	8.2±1.4	7.8±1.1
EBDA/BSA	4.1±0.4	4.2±0.4	4.3±0.4

Pre-MVA: Pre-PMV mitral valve area, Post-MVA: Post mitral valve area, EBDA: effective balloon dilating area, BSA: body surface area, NSR: normal sinus rhythm, AF: atrial fibrillation, All variables are insignificant.

Table 2. Clinical profiles of 3 groups in severe mitral stenosis

	Double (n=58)	Bifoil (n=13)	Inoue (n=15)
Age	40±11	39±11	46±122
Sex	14/45	3/10	3/12
NSR/AF	29/29	8/5	4/11
Pre-MVA	0.8±0.1	0.8±0.2	0.8±0.1
Post-MVA	1.7±0.4	1.6±0.3	1.8±0.3
Echoscore	9.1±1.1	9.0±1.1	8.4±0.6
EBDA/BSA	4.1±0.5	4.2±0.3	4.2±0.5

Abbreviations in Table 1., All variables are insignificant.

lating area and body surface area (EBDA/BSA). The immediate outcomes of the three different balloon groups in overall and in severe MS groups was compared. The key comparison intems were percentages of post-PMV MVA≥1.5 cm^2 by 2 D-echo, increments of mitral regurgitation grade ≥+1 by left ventriculography and percentage of new atrial septal defect (Qp/Qs≥1.5) by oxymetry among these grups. There was no statistical difference in overall and in severe patients in clinical profiles among the three groups. Statistical comparisons between the groups were determined by student t-test, paired t-test, chi-square and Fisher's exact test for the small groups.

RESULTS

The immediate outcomes were compared where

Table 3. Comparison of immediate outcome between double, bifol and inoue balloon in overall patients.

	Double (n=161)	Bifoil (n=34)	Inoue (n=35)
MVA (cm^2) ≥1.5	134 (83%)	29 (85%)	31 (89%)
MR(≥+1)	53 (33%)	16 (47%)	9 (29%)
ASE (Qp/Qs ≥ 1.5)	21 (13%)	9 (26%)	3 (9%)

MVA: mitral valve area, MR: mitral regurgitation, ASD: atrial septal defect, *: $p<0.05$ Bifoil vs Inoue

Table 4. Comparison of immediate outcome between double, bifol and inoue balloon in severe mitral stenosis

	Double(D) (n=58)	Bifoil(B) (n=13)	Inoue(I) (n=15)
MVA ≥ 1.5 cm^2	42 (72%)*	6 (46%)	10 (67%)
MR(≥+1)	27 (47%)	9 (69%)*	4 (27%)
ASE (Qp/Qs ≥ 1.5)	10 (17%)	6 (46%)*	2 (13%)

$p>0.05$, Abbreviations in Table 2.

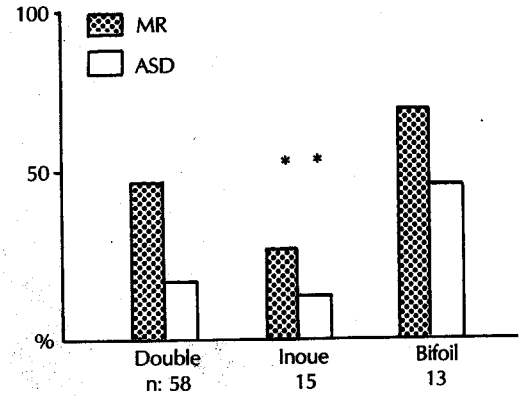

Fig. 3. *Complications in the severe mitral stenosis group. (*: $p<0.05$, Inoue VS Bifoil)*

the mitral valve area was greater than 1.5 cm^2, the increment of mitral requrgitation was greater than grade 1/4 and the atrial septal defects ratio was Qp/Qs≥1.5. in overall patients and in severe groups (Table 3, 4, Fig. 3). In overall patients, there was no statistical difference of post-PMV MVA among the three groups, however, there was signif-

icantly higher occurance of ASD in Bifoil (26%) than Inoue (9%) balloon technique (Table 3). In severe MS patients, the double (72%) balloon group showed significantly better results than the Bifoil (46 %) balloon group with a post mitral valve area greater than 1.5 cm^2 and there were higher incidences of complications such as mitral regurgitation (69%) and atrial septal defects (46%) in the Bifoil balloon than those (27% and 13% respectively) of the Inoue balloon group. However, there was quite comparable outcomes between the double and Inoue balloon groups in post PMV-MVA and complications (Table 4).

DISCUSSION

Percutaneous mitral valvuloplasty has become an accepted therapeutic modality for mitral stenosis using single or double balloon by antegrade (Mckay *et al.* 1987; Lock *et al.* 1985; Vahanian *et al.* 1989) or retrograde approcah (Babic *et al.* 1986). The most important determinant factors include which method is more efficious, cost-beneficial with simpler and fewer complications. There were some reports of sporadic use of the single and double balloon methods and their benefits and faults. Zaibag (1986) and Palacios (1987) recommended the double balloon technique as the method of choice becuses it produces a better mitral valve area after balloon dilatation. The major cause of balloon size. The largest balloon available at that time was 25 mm in diameter, and the effective balloon dilating area between single and double balloon was quite incompatible in previous studies (Palacios *et al.* 1987; Zaibag *et al.* 1986). The inequality of ratio of the effective balloon dilating area and body surface area is the major limitation of these studies. Herrmann (1989) performed gradual dilatation of the mital valve using a single balloon up to 30 mm in diameter and demonstrated the post PMV-MVA did not relate to the method used but to the balloon diameter. There was another preliminary report (Manga *et al.* 1989) of no different outcomes between the double and the Bifoil balloon tecniques in a limited number of patients. Bassand (1990) insisted that there was also a comparable outcome between the double and Inoue balloon techniques. It is difficult to find specific comparison data with the same criteria or parameters among a large number of patients despite the fact that a few authors (Babic *et al.* 1986; Inoue *et al.* 1989; Palacios *et al.* 1987) have presented their data

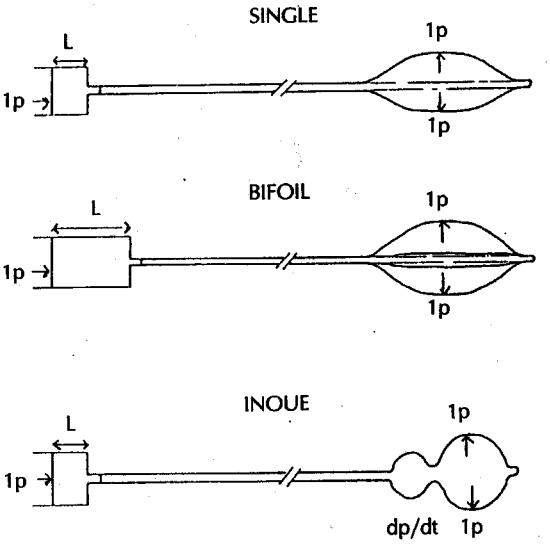

Fig. 4. *Delivery of energy in different balloons.*

about before and after PMV-MVA and complications. Therefore, based on previous literature, it is difficult to make a comparison among these three types of ballooning and therefore it is important to verify which method is more reliable. To determine these aspects, we analysised the data from the recent PMVs done last one year and a half period retrospectively at Severance Hospital, Yonsei University College of Medicine. We compared our results with those of Vahanian (1989). The percentage of post PMV-MVA ≥ 1.5 cm^2 in Vahanian's was 88% in double ballooning and 69% in Trefoil ballooning in 200 patients. The results of double ballooing was similar to our data (85%) and that of Trefoil was lower than the Bifoil (85%) ballooning results seen in our study.

The dilation physics of the different balloons was reviewed: in the single balloon a certain amount of power applied to the syringe was delivered to the balloon wall equally; in the Bifoil balloon the power was delivered in the same way, but more volume was needed due to the larger balloon capacity; therefore, more work was needed for the Bifoil balloon than for the single balloon. In the Inoue balloon the power delivery was the same, but the effectiveness of power dlivery on the proximal portion of the balloon was was the best among the three types of balloons. Therfore, efficiency of work was found to be the best in Inue, followed by the single and Bifoil methods (Fig. 4).

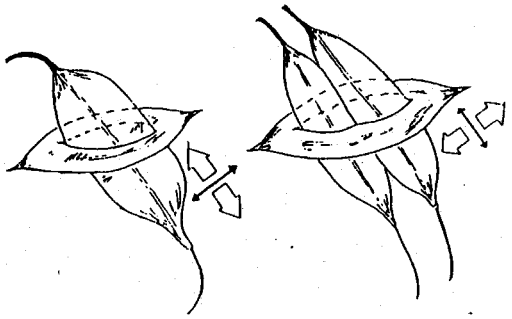

Fig. 5. *Major force direction between single and double balloon.*

Another important determinant factor in ballloon dilation was direction of major force. The direction of major force in the single balloon was toward the leaflet side rather than the commissure side; but, in the double balloon the direction was the oppostie of the single balloon (Block *et al.* 1987; Palacios *et al.* 1987) (Fig. 5). Therefore, the basic mechanism to separate the fused commissure is more effective in the double balloon than in the single balloon. The dilation mechanism of the single balloon is quite similar to that described at length in closed and open mitral commissurotomy (Heger *et al.* 1979; John *et al.* 1983; Nathaniels *et al.* 1970).

Therefore, several factors can be considered to predict a good outcome. The first is balloon size in any type of balloon such as EBDA/BSA. The second is the effectiveness of power delivery, and the third is the major force direction of power on the stenotic valve. Balloon stability on valve leaflets may be another point effecting good results. Balloon stability might be better in the double and Bifoil balloon methods than in the Inoue or single balloon methods because the balloon need not change position in the double or Bifoil but must be adjusted during inflation in the Inoue balloon. Sometimes the Inoue balloon is pulled back into the left atrium. This action could cause mitral regurgitation or chordae tendinae rupture. Two of our cases were operated on several weeks after PMV to correct severe mitral regurgitation. Operative findings included secondary chordae tear and papillary muscle rupture. In our experience, such severe damages on valve apparatus was not encountered on the operating table in the double balloon series. It has suggested that hypereffective delivery of power to the balloon might cause the rupture or tear of a leaflet rather than separation of fused commissure, and improper positioning of the balloon and the pulling of the balloon back from the left ventricle into the left atrium makes mitral mitral regurgitation occur more frequently (18). Severe mitral regurgitation after ballooning was 4% (11) after double ballooning, 1.4% after Inoue ballooning (1989) and 4.0% in our overall series.

Atrial septal defect (ASD) produced after PMV is not as serious a problem in general (Erny *et al.* 1989; Vanderperren *et al.* 1990); however, ASD is detecthed in almost all cases of PMV by transesophageal echocardiography, even though there is no significant increase of oxygen step-up by oxymetry (Kyo *et al.* 1990). Iatrogenic ASD has been observed less frequently in the Inoue balloon than the Bifoil; this was due to the manufacturing problems such as bulky volume after deflation in the Bifoil balloon. ASD interferes with accurate cardiac output by thermodilusion and Fix method; therefore inaccurate measurement of mitral valve area after PMV followed (Petrossian *et al.* 1991).

In conclusion, all three methods are generally effective in relieving mitral stenosis. In severe MS group, the double balloon and Inoue balloon techniques seem to produce comparable outcomes, and both are more effective than the Bifoil balloon. Although our series was relatively small, we found there was a tendency toward a lower complication rate such as atrial septal defect or mitral reguritation by the Inoue balloon technique. Our results suggest the use of a different balloon technique depending on valve pathology. In more severe thickening of the leaflet side and subvalvular structure, the double balloon techniuqe is recommended; in lesser severe valves and lower echoscore valves, the Inoue balloon technique is better because the procedure is simpler than the double balloon technique. In severe calcified and immobile valves, surgery is recommended as the primary procedure. Another randomised prospective study is needed to compare the double and the Inoue ballooning techniques.

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