

ORIGINAL ARTICLE

Comparison of Outcomes of Different Balloon Sets in Patients undergoing Percutaneous Transvenous Mitral Commissurotomy – Bigger and Differ is Better!

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Citation:

Farman MT, Hashim M, Khan N, Saghir T. Comparison of Outcomes of Different Balloon Sets in Patients undergoing Percutaneous Transvenous Mitral Commissurotomy – Bigger and Differ is Better!. PJCVI. 2022; 2(2): 42-51

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DOI: 10.58889/PJCVI.3.42.51

Funding:

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflicts of Interests:

The authors have declared that no competing interests exist.

Received 08/10/2022

Accepted 12/08/2022

First Published 01/12/2022

Abstract

Background: Although for PTMC in patients with severe MS, Inoue balloon technique is claimed to be more common worldwide but in our centre Bonhoeffer multi-track (double balloon technique) system is used. It is, however, not known that which size of balloon set is more suitable in terms of favorable outcomes. The current study aims to determine the outcomes of different balloon sets using in Percutaneous Transvenous Mitral Commissurotomy (PTMC) in symptomatic patients with moderate to severe mitral stenosis (MS).

Methodology: A total of 203 consecutive patients were included. 14x14mm balloon set was used in 154 patients and 14x16mm in remaining 49 patients. PTMC was considered successful in case of achieving MVA ≥ 1.5 cm² with no more than mild MR. Patients developing more than mild MR and valve area <1.5 cm² considered unsuccessful.

Results: Post procedural analysis showed significantly greater achievement in valve area with 14x16mm balloon set (2.96 ± 0.84 cm² versus 3.26 ± 0.95 cm²; $P=0.024$). While trend towards lesser post procedural mean pressure gradient across mitral valve was observed with 14x16mm balloon set (6.05 ± 2.19 mmHg versus 5.47 ± 2.24 mmHg; $P=0.107$). No significant difference in post procedure MR, tamponade and procedure failure was observed. However non-significant difference in success rate (87.7 % with 14x16mm balloon set versus 77.9 % with 14x14mm balloon set; $P=0.153$) was observed among the groups.

Conclusion: Balloon set of size 14x16 mm, may be a better and safe strategy especially in taller and elder patients with bigger annulus size.

Keywords

Percutaneous Transvenous Mitral Commissurotomy, Double Balloon Technique, Outcome.

Introduction

In rheumatic heart disease (RHD) the most frequently affected valve is Mitral Valve. In nearly half of patients other heart valves are also affected along with Mitral valve. However, in 25% of patients Mitral valve is solely affected^{1,2}. Mitral stenosis is more common in female while in contrast mitral regurgitation is more common in male. Also, male are commonly affected from aortic valve disease than female resulting in higher morbidity and mortality³.

Depending upon the symptomatology of the patient, nature and severity of MS and particularly the valve morphology, these patients can be treated conservatively with medical management, and invasively with percutaneous transvenous mitral commissurotomy (PTMC) or surgical replacement of the valve⁴. Inoue K and his colleagues were the first to perform percutaneous trans mitral commissurotomy (PTMC) in 1982. Since then, PTMC became a procedure of choice in patients with suitable anatomy⁵. According to AHA/ACC Guideline for the management of patients with valvular heart disease PTMC is recommended as a Class I indication for symptomatic patients with severe MS (mitral valve area <1.5 cm) and favorable valve morphology in the absence of left atrial thrombus or moderate to severe MR⁶.

PTMC produces significant change in mitral valve morphology⁷. There are two main percutaneous techniques that are practiced around the world. The most popular one is the balloon technique and the older one is metallic commissurotomy that is almost obsolete now a days. Balloon commissurotomy has two major types, the double Balloon (Bonhoeffer) and the single balloon Inoue technique. The later has become the most popular world wide⁸ for the patients with MS favorable for it⁹. Other balloon techniques are: (a) Double balloon technique. (b) Multitrack technique which is the refinement of the double balloon technique also described by Bonhoeffer et al¹⁰. Metallic commissurotomy was introduced by Cribier et al in 1990s¹¹. Although it is a cost effective technique but carries a high risk of

tamponade due to a stiff guide wire in LV cavity which can cause haemopericardium. This technique is now very rarely used¹.

Effectiveness of using Inoue balloon in kids and young adults is already well-known and well established, but its success in elderly patients is not well described in the literature. Although PTMC is reasonable for asymptomatic patients with very severe MS (MVA <1.0 cm²) and with favorable valve anatomy in the absence of left atrial clot or moderate to severe MR. But in elderly patients' valves are deformed, calcified and fragile and hence are less suitable for balloon dilatation¹².

Immediate outcome of PTMC can be predicted from mitral valve morphology as was shown in various studies. However, regarding procedural success and hemodynamic effects of PTMC very few studies have been done in our part of the world and data from Pakistan is not adequate¹. The Wilkins scoring system is considered an established method and is widely used around the world for predicting the outcome of PTMC¹³⁻¹⁵. However, there are few studies that have questioned the accuracy and validity of this scoring system as a predictor of outcomes¹⁶⁻¹⁹.

Percutaneous techniques for mitral valvotomy that are being used in different centers are variable including the Inoue technique, the transseptal transarterial approach and the non-transseptal retrograde arterial approach. With each of the technique satisfactory results have been reported in literature. There is controversy about the superiority of these two above mentioned techniques. Although Inoue technique is technically less demanding than the double balloon technique, the latter is still commonly used in our center. However, it was not known that which combination of balloons is better in terms of hospital outcome. Therefore, the purpose of this study was to compare the immediate outcome of the patients undergoing PTMC using different balloon sets. This study is of particular importance given that to the best of our knowledge no study has been conducted to date to know about the outcomes of PTMC with

double balloon technique using different balloon combinations.

Methodology

This cross sectional prospective study was conducted at catheterization laboratory of the tertiary care cardiovascular teaching hospital at Karachi, (Pakistan) from 1st January 2011 to 31st June 2019. A total of 203 consecutive patients of both gender with age 18 to 50 years with significant mitral stenosis and having Wilkins score ≤ 8 were included in this study. Patients with more than mild mitral regurgitation (MR) and/or having thrombus in left atrium were excluded from the study. Selection of balloon size was on discretion of operator. However, 3 out of 6 operators used 14x14mm balloon set as a default balloon set while others used 14x16 combination.

All the procedures were performed under local anesthesia, if needed moderate sedation was given with midazolam. Routinely during the procedure in Cath Lab pre and post PTMC invasive hemodynamics including Right atrial (RA), Right ventricle (RV), left ventricular end-diastolic pressure (LVEDP), and transmitral pressure gradients (PG) were calculated and the nurse was dedicated to document all the details who was blinded from the study objectives. Interatrial (septal) puncture was done in lateral projection with Brockenbrough needle at 4o clock to 6o clock at fossa ovalis level. Successful entry into the left atrium was confirmed by giving contrast injection into the LA and by looking the pressure tracing. After septal puncture intravenous (IV) 5000 IU heparin was given to all patients.

The other procedural detail of PTMC using double balloon technique has already been described elsewhere in literature and also in our previous publication. After placing the balloons across the mitral valve single or multiple inflations were given. After each inflation, balloon was withdrawn in LA to measure LA pressure or to assess MR on

echo color Doppler. Abrupt increased in LA or pulmonary artery (PA) pressure, suggests acute severe MR. The procedure was ended when either adequate increase in mitral valve area or increase in degree of MR or decrease in mitral valve gradient was observed.

PTMC was considered successful in case of achieving mitral valve area (MVA) of ≥ 1.5 cm² with no more than mild MR. Patients developing more than mild MR and valve area of < 1.5 cm² considered unsuccessful. Failure of PTMC procedure due to tamponade or death was also considered unsuccessful.

SPSS version 21 was used for data analysis. Descriptive statistics were calculated. Quantitative variables were presented in-terms of Mean \pm SD whereas qualitative variables were presented in-terms of frequency and percentages. Independent sample t-test was applied to check significance of mean difference in quantitative variables among the balloon sets. Chi-square test was applied to check association between categorical variables. P value ≤ 0.05 was considered as significant in all analysis.

Results

Out of 203 PTMC procedures, 14x14 mm balloon set was used in 154 (75.8 %) patients and 14x16 mm in remaining 49 (24.1%) patients. 14x16 mm balloon set was used in little bit aged (28.6 ± 9.31 years versus 31.04 ± 8.6 ; $P=0.105$) and taller patients (153.84 ± 7.31 cm versus 157.12 ± 7.51 cm; $P=0.007$). Similarly, 14x16 mm balloon set was more frequently used in patients with bigger annulus size (32.70 ± 2.39 mm versus 34.39 ± 2.04 mm; $P=0.000$) while the mitral valve area was also different in both groups (0.84 ± 0.25 cm² versus 0.91 ± 0.25 cm²; $P=0.086$). Rest of the clinical, echo and Cath features were approximately same in both groups (Table-1).

Table 1: Baseline demographic and pre-procedural Echocardiographic and Catheterization features of patients undergoing PTMC with different sets of balloon

		Balloon set 14x14 n (%) 154(75.9)	Balloon set 14x16 n(%) 49(24.1)	p - value
		Mean ± SD		
Age in years		28.6±9.31	31.04±8.6	0.105
Height		153.84±7.31	157.12±7.51	0.007*
Weight		50.26±10.29	52.61±10.28	0.165
Echo features	Annulus size [mm]	32.70±2.39	34.39±2.04	0.000*
	MVA [cm ²]	0.84±0.25	0.91±0.25	0.086
	RV pressure [mmHg]	68.75±19.58	68.63±21.34	0.972
	MPG across MV [mmHg]	16.40±4.52	15.80±4.61	0.421
	LA size [mm]	47.16±6.18	47.63±5.41	0.629
Cath Findings	RV systolic pressure [mmHg]	76.14±22.50	74.26±19.6	0.601
	Mean LA pressure [mmHg]	32.03±7.93	32.33±7.51	0.815
	LVEDP [mmHg]	12.42±3.73	13.41±3.25	0.098
	Mean PG across MV [mmHg]	19.64±7.98	18.90±7.8	0.568
		n(%)		
Gender	Male	34(22.0)	15(30.6)	0.252
	Female	120(77.9)	34(69.3)	
Previous commissurotomy	Yes	4(2.5)	0(0.00)	0.574
	No	150(97.4)	49 (100)	
History of CVA	Yes	1(0.6)	1(2.0)	0.425
	No	153(99.3)	48(97.9)	
History of A. Fib	Yes	7(4.5)	3(6.1)	0.707
	No	147(95.4)	46(93.8)	
Mitral Regurgitation	Yes	35(22.7)	15(30.0)	0.216
	No	119(77.2)	34(22.2)	
Tricuspid Regurgitation	No/Mild	100(64.9)	28(21.9)	0.396
	Moderate/Severe	54(35.0)	21(28.0)	
LV dysfunction	No/Mild	144(93.5)	45(23.8)	0.747

	Moderate/Severe	10(6.4)	4(28.6)	
Calcification on Fluoroscopy	No Calcium	143(92.8)	43(87.7)	0.251
	+1 / +2	11(7.1)	6(12.2)	

*P-value<0.05 indicating significant results

PTMC= Percutaneous transvenous mitral commissurotomy; CVA= Cerebro vascular accident; AF= Atrial Fibrillation; MVA= Mitral valve area; RV= Right ventricle; MPG= Mean pressure gradient; MV= Mitral valve; LA= Left atrium; LVEDP= Left ventricular end diastolic pressure; LV= left ventricle

Post procedural analysis showed significantly greater achievement in valve area with 14x16mm balloon set (2.96 ± 0.84 cm² versus 3.26 ± 0.95 cm²; $P=0.024$). While trend towards lesser post procedural mean pressure gradient across mitral valve was observed with 14x16mm balloon set (6.05 ± 2.19 mmHg versus 5.47 ± 2.24 mmHg; $P=0.107$). No significant difference in post procedure MR, tamponade and procedure failure was observed. However non-significant difference in success rate (87.7% with 14x16mm balloon set versus 77.9% with 14x14mm balloon set; $P=0.153$) was observed among the groups (Table 2).

Table 2: Technical and Post procedural catheterization and echocardiographic features of patients underwent PTMC

Technique of procedure		Balloon set 14x14 n (%)	Balloon set 14x16 n(%)	P - value
		154(75.9)	49(24.1)	
Mean \pm SD				
Catheterization features	RV systolic pressure [mmHg]	55.87 \pm 17.23	52.39 \pm 13.13	0.196
	Mean LA pressure [mmHg]	17.80 \pm 5.62	18.69 \pm 5.22	0.328
	LVEDP [mmHg]	15.01 \pm 4.35	16.65 \pm 4.74	0.025*
	Mean PG across MV [mmHg]	3.08 \pm 3.31	2.53 \pm 2.61	0.292
Echocardiographic Features	MVA [cm ²]	2.96 \pm 0.84	3.26 \pm 0.95	0.024*
	Mean PG across MV	6.05 \pm 2.19	5.47 \pm 2.24	0.107
	PA pressure	37.80 \pm 14.41	36.80 \pm 13.46	0.666
n(%)				
Position of wire	Descending aorta	51(33.1)	18(36.7)	0.480
	Ascending aorta	58(37.6)	21(42.8)	
	LV apex	45(29.2)	10(2.4)	
Number of balloon inflation	Once	15(9.7)	3(6.1)	0.571
	Twice or more	139(90.2)	46(93.8)	
Post PTMC MR	No / Mild	141(91.5)	45(91.8)	1.000
	Moderate / Severe/ Mild to Moderate	13(8.4)	4(8.4)	
Post PTMC TR	No / Mild	123(79.8)	37(75.5)	0.549

	Moderate / Severe/ Mild to Moderate	31(20.1)	12(24.4)	
Tamponade		4(2.5)	2(4.0)	0.633
No of patients with MVA of <1.5cm²		5(3.2)	1(2.0)	1.000
Successful PTMC		120(77.9)	43(87.7)	0.153

*P-value<0.05 indicating significant results

PTMC=Percutaneous transvenous mitral commissurotomy; RV= Right ventricle; LA= Left atrium; LVEDP= Left ventricular end diastolic pressure; PG= Pressure gradient; MV= Mitral valve; MVA= Mitral valve area; PA=Pulmonary artery; MR= Mitral regurgitation; TR=Tricuspid regurgitation

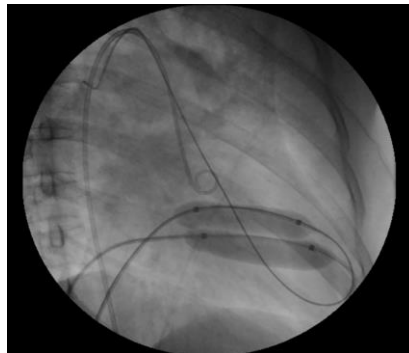


Figure 1: Double Balloons across mitral valve

Double Balloons across mitral valve are seen. Balloons are in inflating position for valvuloplasty. PTMC wire is seen across the atrial septum through mitral valve and LV up in the ascending aorta for good support (Figure 1).



Figure 2: Short axis echocardiographic view showing severe mitral valve stenosis



Figure 3: Post PTMC short axis echocardiographic view showing good opening of mitral valve and good opening of mitral valve commissures.

Discussion

Mitral stenosis is mostly rheumatic in origin in the developing countries of south-east Asia including Pakistan. It is more common in female due to unequal socioeconomic norms, lack of facilities, and overcrowding. After the first mitral valvuloplasty done by Inoue et al in 1984, Percutaneous Mitral Balloon Valvuloplasty (PMBV) or PTMC is the treatment of choice for symptomatic patients with moderate to severe mitral stenosis^{20, 21}.

In 1999, Dr. Philipp Bonhoeffer published a paper and described the refinement of using double balloon technique for treating moderate to severe mitral stenosis on multi-track system²¹. This technique was used in 100 patients of 13 different countries by 9 operators. The results were successful and only one patient had got significant mitral insufficiency after the procedure²¹. Since then, Bonhoeffer double balloon multi-track system is considered a valid alternative of treating Mitral Stenosis. In our Centre this technique is also being used since last 20 years.

The conventional double balloon technique was considered technically more difficult, but it was proved more successful in improving mitral valve area comparing the results of Inoue Balloon technique^{22,23}. However, after the refinement done by Bonhoeffer et al. the procedure has become user friendly and can be carried out with 30 minutes²¹. Hence, in few studies it has been observed superior in results in comparison to Inoue technique²⁴⁻²⁶. Although comparing two techniques is out of scope of this article, we were interested to compare the use of two different sets of balloons for treating mitral stenosis by using this Bonhoeffer multi track double balloon system. We found that by using different balloon sets we can achieve better mitral valve area ($2.96 \pm 0.84 \text{ cm}^2$ with 14x14 mm balloon sets versus $3.26 \pm 0.95 \text{ cm}^2$ with 14x16 mm balloon sets; $P=0.024$). This is an interesting and at the same time an encouraging finding that we got with no additional cost of significant mitral insufficiency or any other notable complication. The possible

reason behind the better results with different size balloon sets is the oval shape mitral valve orifice that better complies with different sets of double balloons, rather than rounded Inoue or same set of balloons. The mean age of current study population was 28.6 ± 9.31 years among patients who used Balloon set 14x14 mm and 31.04 ± 8.6 years among those who used Balloon set 14x16 mm. Meaning that the group who had 14x16 mm balloon set was slightly aged, but this difference was insignificant ($P=0.10$). However, Height of the patients of both groups were significantly different (153.84 ± 7.31 cm with 14x14 mm balloon set versus 157.12 ± 7.51 cm with 14x16 mm balloon set; $P=0.007$). This is another interesting finding that we got in our study, and it predicts that with increasing age and tall body habitus we may get better results with different double balloon set. Similarly, mitral valve annulus size was different in both groups (32.70 ± 2.39 mm with 14x14 mm balloon set versus 34.39 ± 2.04 mm with 14x16 mm balloon set; $P=0.000$). This is again in the line of our observation that with bigger annulus or orifice size a double balloon set with different sizes may be more accommodative and may give us better results as compared to Inoue or same size balloon. Even with bad morphology of the valve double balloon technique with different sizes observed better in outcome in terms of achieving better mitral valve area and less complications.

The most feared complication of PTMC is the development of significant mitral insufficiency and tamponade. The frequency of development of significant mitral regurgitation (MR) in our study was 8.4 % in both the groups. This includes the MR that was mild to moderate and tolerable in terms of symptoms. Unfortunately during data collection, we could not separate more than mild MR by Moderate or severe MR. But these were the patients who were having more than mild MR with stable symptoms and most of them did not require surgery. However, keeping view at our study objective we can report it with certainty that by using double balloon technique of different sizes the risk of increasing MR is negligible. The difference of developing Tamponade was also

non-significant in both groups (2.5 versus 4.0 %; $P=0.63$).

Failure of PTMC procedure is decreasing in frequency with the passage of time as physicians are achieving experience with the use of techniques and refinement of hardware and skills. Frequency of success of the PTMC in our study was 77.9% among patients in which we used balloon set 14x14 mm whereas the success rate of the PTMC was 87.7% among patients in whom we used balloon set 14x16 mm. The patients in which we could not achieve MVA more than 1.5 cm² was 3.2 versus 2.0 % ($P=1.0$). This is non-significant and overall comparable rates reported in the study conducted by Ahmad et al from Lahore whose failure rate was 6.6% in patients with mitral valve disease (Wilkin's echo score <8)²⁷.

The effect of successful PTMC on global RV systolic and diastolic functions in patients with rheumatic MS has not been well-defined. It has been reported that pulmonary PA pressure normalizes within six months but may stay elevated for more than two years in some patients²⁸. Improvement in Tricuspid regurgitation (TR) and PA pressure is an important predictor of successful PTMC in mitral stenosis patients. In our study Pre PTMC moderate or severe TR was reported 35.0 % versus 42.8 % in balloons of 14x14 and 14x16 mm respectively. The significant improvement was observed after PTMC, and moderate or severe TR was observed in just 20.1 % in patients in whom 14x14 mm balloons were used and 24.4 % in patients in whom 14x16 mm balloon set was used. Post PTMC PA pressure was 37.80 ± 14.41 among patients used balloon 14x14 mm whereas the PA pressure after PTMC among patients who used balloon set 14x16 mm was 36.80 ± 13.46 . These findings were in accordance with Gul et al, Drighil et al and Ekinic et al^{29, 30}. As mentioned earlier PA pressure may take 6 months to 2 years to become normalizes.

Conclusion

Bonhoeffer multi-track double balloon technique is equally safe and effective for treating moderate to severe mitral stenosis with suitable anatomy. As

far as use of different size of balloon set is concerned, it can be concluded by our study results that among different size of balloon set, the balloon size of 14x16 mm may be used as a better and safe strategy especially in taller and elder patients with bigger annulus size. However, further randomized multicenter studies in larger population are needed to validate our findings.

Acknowledgment

Author wants to pay thanks to the senior faculty members Prof. Khan Shah Zaman and Prof. Ishtiaq Rasool for their continuous support and guidance in doing PTMCs and collection of data for research purpose.

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