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ORIGINAL ARTICLE

A novel technique of multi-track percutaneous balloon mitral commissurotomy (PBMC)

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KEYWORDS

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Abstract *Background and Aim:* Percutaneous balloon mitral commissurotomy (PBMC) has become treatment of choice for severe pliable rheumatic mitral valve stenosis (RMVS). The multi-track system is a recent variant of the double-balloon technique which is easier through the use of the mono-balloon and only a simple, single guidewire approach. In the present study, we sought to use the most metallic wire with multi-track balloon instead of the conventional multi-track wire which make the procedure safer and faster.

Subjects and Methods: We studied 62 consecutive patients (55 females) with significant symptomatic RMVS who underwent multi-track PBMC. They were randomized into 2 groups: the first group included 32 patients treated with the novel multi-track technique using the double coil Inoue metallic wire and the second group includes 30 patients treated with the conventional multi-track technique.

Results: No statistically significant differences were found between both groups regarding any of the studied variables; apart from the pre-procedural MV area which was significantly lower in the novel-technique group compared to the conventional-technique group. None of the patients had cardiac tamponade, systemic thromboembolism or any groin complication. There were neither in-hospital deaths nor complications necessitating emergent cardiac surgery in both groups.

Conclusions: This new technique achieves the double benefit of being safer and easier with Inoue wire and saving excess material with the multi-track system; which is more economic.

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Introduction

Rheumatic mitral valve stenosis (RMVS) still remains an important public health concern in developed countries [1]. When there is favorable MV anatomy, percutaneous balloon mitral commissurotomy (PBMC) has become treatment of choice for severe pliable rheumatic mitral valve stenosis (RMVS) [2]. With increasing experience and better selection

of patients, the immediate results of the procedure have improved and the rate of complications declined [2]. Several randomized trials reported similar hemodynamic results with PBMC and surgical commissurotomy [1,3–6].

There are currently 2 main techniques for PBMC: balloon commissurotomy and metallic commissurotomy. In balloon commissurotomy, the two main modalities are the double-balloon technique and the Inoue technique. The double-balloon technique is effective but demanding and carries risk of LV perforation by the guidewires or the tip of the balloons [7].

The multi-track operator-friendly system is a recent variant of the double-balloon technique which has the advantages of double balloon technique besides making the procedure easier through the use of a monorail balloon and only a simple, single guidewire approach [7,8]. The procedure time easily matches that of single balloon techniques while achieving consistently higher MV area post-dilatation [7]. The mismatch of the round shape of a single balloon with the oval MV orifice probably explains the better results with double balloon dilatation [8].

The Inoue technique, on the other hand, allows for a step-wise dilatation (as it is pressure extensible) leading to safe and fast positioning across the MV [7]. In the present study, we sought to establish a modification of PBMC procedure via using the Inoue metallic wire with multi-track balloon instead of the conventional multi-track wire (Super Stiff, preformed 0.035 in. guidewire), aiming to achieve the double benefit of being safer and easier with Inoue wire and saving excess material with the multi-track system; which is more economic.

Subjects and methods

Study design and participants

The study population consisted of 62 consecutive patients with significant symptomatic RMVS (MV area $< 1 \text{ cm}^2$) who underwent multi-track PBMC solely under fluoroscopic guidance in our institute between January 2010 and December 2011.

The patients were enrolled in this study if the following exclusion criteria were absent: (1) left atrial (LA) cavitory thrombus or unstable (such as pedunculated, mobile) thrombus in the LA appendage; (2) severe MR (vena contracta on color flow mapping of $> 6 \text{ mm}$); (3) severe aortic stenosis (aortic orifice area calculated by the continuity equation of $< 0.7 \text{ cm}^2$); (4) severe aortic regurgitation (the width of the aortic regurgitation jet $> 50\%$ of the width of the LV outflow tract); (5) evidence of significant coronary artery disease (history of myocardial infarction, typical effort angina, or the presence of significant atherosclerotic lesions in the proximal coronary arteries, as demonstrated by transesophageal echocardiography); (6) active systemic infection; and (7) active cerebral hemorrhage or embolism. These patients were divided into 2 groups: the first group with metal Inoue wire and the other group with conventional multi-track wire. Informed consent to participate in this study was obtained from all patients before the PBMC procedure.

Pre- and post-procedural echocardiographic evaluations

Detailed transthoracic (TT) and transesophageal (TE) and echocardiographic (Echo) examinations were done in all

patients using a real-time phased array sector scanner (Vivid-3 model) with an integrated color Doppler system for imaging at 2.5–4.0 MHz with second harmonic capabilities. For continuous and pulsed wave Doppler, the transducer emitted at 1.9 MHz. TE Echo was interfaced with a 5 MHz multiplane probe mounted on an endoscope.

The pre-procedural examination was performed within 48 h before undergoing PBMC. Post-procedural Echo assessment was also carried out. The pre-procedural or post-procedural MV orifice area was calculated by averaging the area determined by planimetry (using two-dimensional TT Echo) with that calculated by the Doppler pressure half-time method [9,10]. Peak and mean pressure gradients across the MV were recorded; and pulmonary artery systolic pressure was estimated using tricuspid regurgitation Doppler signal velocity. The morphologic changes of the MV and MV core were evaluated by the method of Wilkins et al. [11].

The multi-track kit [12]

The kit for mitral dilatation is made of five components (Multi-Track, Mitral dilatation kit, STJMED, Hopkinton, NY). There are two balloon catheters, a multi-track angiographic catheter, a guidewire, and a septal dilator. The system allows one to load two balloon catheters on the same wire. The multi-track angiographic catheter has side holes as functional unit, which enable pressures measurement during the procedure without guidewire removal. Both balloon catheters have stainless steel sheaths connected to nylon tubing. The multi-track balloon has a 10-cm plastic shaft and the balloon with the multi-track tip at its extremity. The other balloon catheter has a standard monorail catheter of 16 cm of length. The guidewire is an extra-stiff 0.035 wire with 6-cm floppy J-tip with preformed curve adapted to deployment at the LV apex. The septal dilator is 65-cm-long 14 Fr tubing with a guidewire lumen and a tapered tip.

Commissurotomy procedure [12]

Right groin was used for vascular access (two 6F sheaths for arterial and venous access). A pigtail catheter is advanced into the aortic root and connected to a pressure-line for monitoring purposes. A 0.032 in. guidewire was introduced through the venous sheath and advanced into the left innominate vein (LIV). A 7F Mullin's dilator (St Jude's Medical, Minnetonka, Minn) was advanced over this wire to LIV in the same view. The 0.032 in. guidewire was exchanged with a Brockenbrough needle that was passed from LIV to the superior vena cava to slide over the inter-atrial septum advanced within the Mullin's dilator just short of its tip. The assembly of the Brockenbrough needle and the Mullin's dilator was then manipulated in the RA in AP and lateral view with the index of the Brockenbrough needle pointing postero-medially (4 o'clock or 5 o'clock position) at the groin until the tip of the Mullin's dilator tented midseptum at or below (but not posterior to [13]) the fossa ovalis (to facilitate catheterization through the stenotic MV); and the atrial septostomy was then done.

After entry of the needle into the LA is confirmed, first by contrast medium injection followed by pressure recording, the needle direction is set toward 3 o'clock (left side of the patient). If there is no or little resistance, the catheter needle is advanced

forward about 2 cm into the LA. Then, the catheter alone is advanced another 2 cm (or until the tip of the sheath meets a resistance at the septum), while the needle is being withdrawn. Upon removing the needle, after the catheter is placed in the LA, 100 IU/Kg heparin is given immediately through the catheter. After baseline hemodynamic studies, PBMC is performed.

The conventional multi-track technique [8]

A balloon endhole catheter is introduced into the Mullin's sheath and advanced into the LA. Before passing through the MV, the balloon of this catheter is inflated in order to avoid its entrapment in the subvalvular apparatus. The MV is then catheterized either directly orienting the catheter slightly anteriorly or by a more indirect approach allowing the catheter to form a large loop in the LA. After the balloon catheter is passed through the MV, it is advanced to the apex of the LV and the catheter is then straightened to obtain a harmonious curve on its shaft. The 0.035 in. stiff guidewire with 6-cm floppy *J*-tip is now positioned through this catheter. Particular attention is paid to allow the *J* to develop freely when exiting the tip of the catheter. After full deployment of the *J*, the wire is pushed into the LV until a good guidewire position is obtained. Guidewire position is considered adequate when the entire 6 cm of floppy tip is pointing upward toward the LV outflow and the curve in the LA is as flat as possible. Then the balloon is deflated and the catheter is retrieved with the Mullin's sheath. The skin and the atrial septum are then dilated with a 14 Fr long dilator.

The balloons of the multi-track System are prepared at this time drawing vacuum and removing air bubbles on each balloon lumen without inflating them. The syringe is then disconnected and filled with a mixture of contrast medium and saline solution and reconnected to the balloon catheters. The septal dilator is now withdrawn and the balloons are loaded over the guidewire. First the multi-track balloon is introduced through the skin and atrial septum and positioned in MV. The second balloon is then advanced over the wire and lined up with the first one in the MV. More than half of the balloon length should be positioned in LV before inflation. However, attention should be paid that the tip of the multi-track catheter does not advance over the floppy part of the wire. The balloons are then inflated simultaneously under fluoroscopic vision. The disappearance of the waist should be observed at this time and confirm adequate position in MV. After deflation, the balloons are sequentially removed under fluoroscopic guidance. After removal of the balloon on the wire, the multi-track balloon should be retrieved maintaining a parallel orientation to the guidewire. To assess the results, the pigtail catheter is again introduced into LV and a multi-track angiographic catheter is connected to the wire and advanced into the LA. If the diastolic gradient is not satisfactory, different balloon sizes of multi-track catheters can be introduced over the wire at this time. Otherwise, with an acceptable transmitral gradient, the wire is pulled into the LA leaving the multi-track angiographic catheter in the LA and the measurements are repeated. This avoids the need to record MR related to the guidewire in the MV. The multi-track system allows measuring the transmitral gradient even through a single venous approach; by gliding two multi-track angiographic catheters along the wire, which is positioned in the MV: one is advanced

into the LV and the other one to the LA. Therefore, the arterial approach routinely used for MV dilatation can be avoided.

The novel multi-track technique

From our experience, the double loop stainless-steel Inoue wire could pass through MV to LV by Mullin's sheath and dilator. After removing the needle from the Mullin's dilator, the double coil metal wire of the Inoue system (Toray Industries Inc., Tokyo, Japan) was introduced through the Mullin's dilator into the LA. With advancing the sheath before the dilator to direct the wire towards the MV orifice, we can cross the MV into the LV by double looped wire instead of the balloon endhole catheter. The loops of the round wire could be easily visualized in the LV under fluoroscopy. However, the fear of the wire-induced arrhythmia, perforation or entrapment in the subvalvular apparatus remains an issue. Nevertheless, apical perforation by this wire is virtually avoided because of its double coil. To be sure that the wire is not entrapped in the subvalvular apparatus, this double coil wire should reach the LV apex with a free to anterior movement in the LV cavity. The remaining steps are essentially the same as in the conventional technique described above.

RESULTS

We studied 62 patients (55 females; 88.7%) with significant symptomatic RHDs who were randomized into 2 groups. The first group included 32 patients (29 females; 90.6%) treated with the *novel multi-track technique*, aged 36.5 ± 9.2 years. The second group includes 30 patients (26 females; 86.7%) treated with the conventional multi-track technique, aged 37.3 ± 13.1 years. Table 1 shows the demographic, clinical, and Echo data of both groups at baseline. As shown in the table, no significant statistical differences were found between both groups regarding any of the studied variables. The majority of patients (44; 71%) had New York heart association (NYHA) class III dyspnea, and 17 patients (27%) had chronic AF on presentation; 8 (25%) in Inoue group and 9 (30%) in endhole group. Only 7 patients (11%) had previous PBMV; 4 (12.5%) in *novel-technique* group and 3 (10%) in *conventional-technique* group.

Self-limiting non-sustained ventricular tachycardia of no hemodynamic or clinical significance occurred in 9 (14.5%) patients; 5 (16%) patients in Inoue group and 4 (13%) patients in endhole group ($p = 0.917$). Failed multi-track PBMV occurred in just 4 cases (2 in each group); which were then dilated successfully with the Inoue balloon. The reasons for this failure included the inability to pass the wire across the MV orifice in 2 cases (one in each method); and the failure to stabilize the double balloon over the wire which passed through the MV orifice in the remaining 2 cases.

Table 2 summarizes the pre- and post-procedural findings and comparisons in the studied groups. As shown in the table, no statistically significant differences were found between both groups in any of the studied variables; apart from the pre-procedural MV area which was significantly lower in the Inoue group compared to the endhole group. Overall, MV area increased significantly after PBMV from 0.98 ± 0.14 to 2.08 ± 0.39 in the Inoue group ($p < 0.001$); and from 1.07 ± 0.18 to 2.11 ± 0.47 ($p < 0.001$) in the endhole group. Also, there was significant reduction of mean transmitral

Table 1 Baseline demographic, clinical, and Echo data in the studied groups.

	Novel-technique (<i>n</i> = 32)	Conventional-technique (<i>n</i> = 30)	<i>p</i> -value
<i>Demographic data</i>			
Age (years)	36.5 ± 9.2	37.3 ± 13.1	0.781
<i>Gender</i>			
Male	3 (9.4%)	4 (13.3%)	0.933
Female	29 (90.6%)	26 (86.7%)	
<i>Clinical data</i>			
<i>NYHA class</i>			
II	8 (25.0%)	10 (33.3%)	0.660
III	24 (75.0%)	20 (66.7%)	
Atrial fibrillation	8 (25.0%)	9 (30.0%)	0.876
Previous MV dilatation	4 (12.5%)	3 (10.0%)	0.928
<i>Echo data</i>			
MV score	7.27 ± 1.16	7.14 ± 1.36	0.686
Left atrial diameter	4.97 ± 0.45	5.17 ± 0.64	0.158
LVESD (cm)	2.89 ± 0.31	3.01 ± 0.33	0.145
LVEDD (cm)	4.65 ± 0.38	4.71 ± 0.31	0.501
<i>Aortic regurge</i>			
No or trivial	28 (86.4%)	27 (90.0%)	0.875
Grade I	4 (13.6%)	3 (10.0%)	

LVEDD: left ventricular end diastolic dimension; LVESD: left ventricular end systolic dimension; MV: mitral valve; NYHA: New York heart association.

Table 2 Comparative analysis of pre- and post-procedural data in the studied groups.

	Novel-technique (<i>n</i> = 32)	Conventional-technique (<i>n</i> = 30)	<i>p</i> -value
<i>MV area</i>			
<i>Pre-dilatation</i>			
Pressure half time method	0.93 ± 0.16	1.08 ± 0.20	0.002**
Planimetry method	1.05 ± 0.14	1.07 ± 0.17	0.209
Average	0.98 ± 0.15	1.07 ± 0.18	0.031*
<i>Post-dilatation</i>			
Pressure half time method	2.17 ± 0.29	2.11 ± 0.48	0.590
Planimetry method	2.01 ± 0.41	2.13 ± 0.45	0.282
Average	2.08 ± 0.39	2.11 ± 0.47	0.785
<i>Mitral regurge</i>			
<i>Pre-dilatation</i>			
No or trivial	23 (71.9%)	20 (66.7%)	0.866
Grade I	9 (28.1%)	10 (33.3%)	
<i>Post-dilatation</i>			
No or trivial	7 (21.9%)	4 (13.3%)	0.150
Grade I	15 (46.9%)	13 (43.3%)	
Grade I-II	9 (28.1%)	11 (36.7%)	
Grade II-III	1 (3.1%)	2 (6.7%)	
<i>Trans-mitral pressure gradient</i>			
<i>Pre-dilatation</i>			
Peak pressure gradient	22.4 ± 5.2	24.6 ± 5.6	0.114
Mean pressure gradient	12.6 ± 3.13	13.7 ± 4.32	0.253
<i>Post-dilatation</i>			
Peak pressure gradient	12.8 ± 3.15	11.9 ± 2.12	0.195
Mean pressure gradient	6.5 ± 2.4	5.8 ± 1.4	0.169
<i>PASP (mmHg)</i>			
<i>Pre-dilatation</i>			
	37.9 ± 16.2	38.3 ± 15.3	0.921
<i>Post-dilatation</i>			
	30.1 ± 14.6	30.2 ± 12.5	0.977

** = *p* < 0.01.

* = *p* < 0.05; PASP: pulmonary artery systolic pressure.

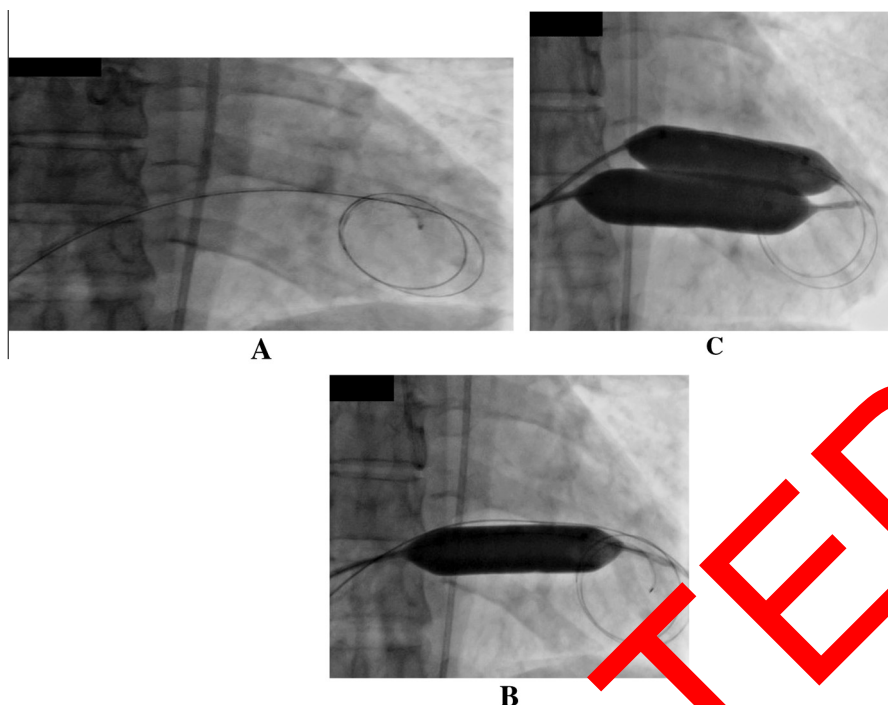


Figure 1 steps of balloon dilatation for case no 11 from novel-technique group. (A) AP view showing the metallic double coil Inoue wire passing thorough from the inter-atrial septum through the MV orifice to reach the LV apex. (B) AP view showing the first monorail multi-track balloon fully inflated over the wire at the MV apparatus. (C) AP view showing both multi-track balloons fully inflated over the wire at the MV apparatus with complete disappearance of the balloon waist.

pressure gradient from 12.6 ± 3.13 to 6.5 ± 2.4 mmHg ($p < 0.001$) in the Inoue group and from 13.7 ± 4.32 to 5.8 ± 1.40 mmHg ($p < 0.001$) in the endhole group.

Before PBMC, 43 patients (69%) had no or trivial MR and 19 (31%) patients had grade-I MR. After PBMC, 11 patients (18%) had no or trivial MR, 28 (45.2%) had grade-I MR, 3 (4.8%) developed grade I-II MR; 9 (14.3%) in Inoue group and 11 (36.7%) in endhole group. Only 3 (4.8%) developed grade II-III MR ($p = 0.15$); but no patient developed severe MR necessitating surgery. Notably, PAS dropped significantly after PBMV; from 29.9 ± 16.2 to 30.7 ± 14.6 mmHg ($p = 0.047$) in the Inoue group; and from 38.3 ± 15.3 to 30.2 ± 12.5 mmHg ($p = 0.029$) in the endhole group.

There was knot formation on the Inoue wire in 2 cases without any further procedural complications. The knot was formed over the Inoue wire proximal to the balloon and was detected after MV dilatation during removal of the balloon from over the wire at the end of the procedure. Managing knot formation was simply done by traction of both balloon and wire together which resulted in no vascular complications.

None of the patients had cardiac tamponade, systemic thromboembolism or any groin complication. There were neither in-hospital deaths nor complications necessitating emergent cardiac surgery.

Fig. 1 shows steps of balloon dilatation for case No. 11 from novel-technique group.

Discussion

This study is the first to use Inoue metallic wire in PBMC with multi-track system. The Inoue technique has become the most

popular worldwide [12]. The design of the Inoue balloon allows easy and fast positioning across the valve. In addition, it is pressure extensible, allowing for the performance of a step-wise dilatation [7]. The available data comparing the Inoue technique and the double-balloon technique suggest that the Inoue technique makes the procedure easier; that both have equivalent efficacy, although the double-balloon technique may result in a slightly larger valve area; that the long-term results are equivalent; and that the Inoue balloon carries a lower risk because LV perforation is virtually avoided [7].

Traditionally, PBMC using multi-track double balloon was always done by Super Stiff, preformed 0.035 in. guidewire. The double-balloon technique is effective but demanding and carries the risk of LV perforation by the guidewires or the tip of the balloons. The multi-track is a recent variant of the double-balloon technique and aims to make the procedure easier through the use of a monorail balloon and only a single guidewire [7]. This has the advantages of double balloon technique besides the fact that the procedure times easily match those of single balloon technique while achieving consistently higher MV area post-dilatation. The mismatch of the round shape of a single balloon with the oval MV orifice probably explains the better results with double balloon dilatation [8].

The conventional multi-track wire needs balloon endhole catheters to pass the conventional 0.035 in. guidewire from LA to LV after septostomy [8]. Some centers (including ours) use right Judkins catheter to pass from LA to the LV; which is more traumatizing than the endhole catheter. Besides, there is a fear of entrapment in subvalvular apparatus; with increased incidence of LV perforation. The metallic wire of Inoue balloon used in this study is very unliable to be trapped in the subvalvular apparatus because of its free to and fro movement in

the LV cavity; or to cause LV apical perforation because of its double coil; thus minimizing the higher incidence of traumatic injuries by multi-track system compared to the Inoue balloon system.

In our study, there was no difference between both groups of PBMV in short term results; with no cases of severe MR necessitating surgical interference, LV perforation, or cardiac tamponade.

The cost of PBMV is a great problem for treating MS since this disease is endemic in low socioeconomic environments. To solve this issue, Cribier et al. [14] and Arora et al. [15] have developed a percutaneous metallic device for MV dilatation, which can be autoclaved and reused. In fact, the cost of the multi-track system is reduced due to the simplicity of the system [8]. In addition to the above-mentioned economic advantages of the multi-track system, our new technique is far more economic regarding saving material and time; because balloon endhole catheter is costly and, on the other hand, Inoue wire can be reused after sterilization.

Limitations of the study

This an initial feasibility study including a small number of patients, authors recommend a larger trial to prove the beneficial effects of this novel technique on large scale especially, we have a long waiting list of many patients with symptomatic RMS in need for effective, safe and affordable non-costly therapy.

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