Indian Heart Journal 69 (2017) 176–181

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Original Article

Percutaneous balloon valvuloplasty with Inoue balloon catheter technique for pulmonary valve stenosis in adolescents and adults

Charan Lanjewar, Milind Phadke, Arvind Singh*, Girish Sabnis, Mahesh Jare, Prafulla Kerkar

Department of Cardiology, Seth G.S. Medical College & King Edward VII Memorial Hospital, Mumbai, India

ARTICLE INFO

Article history:
Received 29 July 2016
Accepted 10 November 2016
Available online 1 March 2017

Keywords:
Adult congenital heart disease
Valvular heart disease
Pulmonary valve intervention
Balloon procedures

ABSTRACT

Background: Percutaneous balloon pulmonary valvuloplasty is the procedure of choice for uncomplicated severe or symptomatic pulmonary stenosis. The present study describes our experience in balloon pulmonary valvuloplasty using the Inoue balloon catheter in adolescent and adult patients.
Aims: To assess the immediate and mid-term outcomes of percutaneous balloon valvuloplasty with Inoue balloon catheter in adolescent and adult patients.
Methods and results: Between June 2010 and July 2015, we performed percutaneous balloon pulmonary valvuloplasty with Inoue balloon catheter in 32 patients (59.37% females) aged 8 to 54 years (mean 23.6 ± 11.5). Following the procedure, the mean right ventricular systolic pressure and the pulmonary valvular peak-to-peak systolic gradient decreased from (121.6 ± 42.4 to 61.19 ± 24.5 mmHg, $p = 0.001$) and (100.9 ± 43.3 to 36.4 ± 22.5 mmHg, $p = 0.001$), respectively. Twenty patients (Group A) showed immediate optimal results with post-procedure peak systolic gradient <36 mmHg while 12 patients (Group B) had suboptimal results. An increase in pulmonary regurgitation by one grade was detected in 17 patients (53.2%). Twenty-three patients available for follow-up (mean duration, 2.75 years [range 0.25–5 years]) had a mean residual peak gradient of 23.6 ± 2.51 mmHg on Doppler echocardiography with attenuation of reactive RVOT stenosis in all Group B patients. There was no further increase in grade of pulmonary regurgitation or restenosis on mid-term follow-up.
Conclusion: Percutaneous Inoue balloon technique is an attractive alternative with excellent mid-term results for adolescents and adults with isolated pulmonary stenosis.

1. Introduction

Pulmonary valve stenosis (PS) is relatively common disease, and may also be diagnosed in adults, with an incidence of 0.12 per 1000 adults.[1] The presentation may be mild (mostly asymptomatic), moderate (dyspnoea on exertion and fatigue), or severe (right ventricular failure and cyanosis). Since the first transcatheter balloon pulmonary valvuloplasty (BPV) by Kan et al.,[2] it has become the procedure of choice for children and adults with uncomplicated severe or symptomatic PS.

Current approaches to BPV utilise various fixed size balloon catheters using a single or a double balloon technique. Use of double or triple balloons have the disadvantage of prolonged procedural time, stretch-induced injury to vessels, balloon slippage and more frequently injuring the pulmonary valve.[3]

The Inoue balloon is a unique balloon designed specifically for dilation of the mitral valve.[4] It is manufactured with two layers of latex and a fine layer of nylon mesh sandwiched between them. Inoue balloons are available in multiple sizes from 20 to 30 mm varying in 2 mm increments. The balloons have burst pressures from 4 atm for the 20 mm diameter Inoue balloon decreasing to 2 atm for the 30 mm diameter balloon. Each catheter can be safely inflated to a maximal diameter of 1–2 mm above the nominal size because of the built-in safety margin.

The use of the Inoue balloon, first reported by Lau et al.[5] has advantages over the single-balloon technique. Unlike the cylindrical balloon catheter, with its stiff tip and long balloon, the Inoue balloon catheter is flexible and short, thus minimising the extent of injury to the RV outflow tract and the MPA.[5] Double balloon technique is more complex due to one balloon snagging on the other when both are positioned side by side across the annulus. Moreover, due to its short and self-positioning characters, it minimises possible injury to the right ventricular (RV) infundibulum or the main pulmonary artery (PA).[6] The adjustable inflation of

* Corresponding author.
E-mail address: drarvindsingh030207@gmail.com (A. Singh).

http://dx.doi.org/10.1016/j.ihj.2016.11.316

the Inoue balloon makes stepwise dilation possible, reducing the risk of over-dilation of the pulmonic valve. This is not possible with the cylindrical balloon catheter as it wrinkles after inflation and loses its low profile shape. A further advantage of the Inoue balloon arises from its short inflation–deflation cycle of approximately five seconds. This takes care of haemodynamic compromise resulting from the complete obstruction of right ventricular outflow during inflation of the balloon. All these advantages of the Inoue balloon catheter make procedures simpler, safer, and faster.[5,7]

There is scant Indian data on Inoue balloon catheter technique for PS. The present report describes our experience in BPV using the Inoue balloon catheter and its immediate and mid-term results in adolescent and adult patients. To our knowledge this is the largest data from India with mid-term follow-up of patients undergoing BPV with Inoue balloon catheter.

2. Methods

2.1. Study patients

From July 2010 to May 2015, 32 consecutive adolescent or adult patients underwent BPV with an Inoue balloon catheter. Patient selection was based on symptoms and/or signs and investigations supporting significant isolated PS. All patients had an electrocardiogram (ECG), chest radiograph, and transthoracic echocardiography (TTE) studies done prior to the procedure.

Balloon valvotomy was planned in asymptomatic patients with echocardiographic evidence of doming of the pulmonary valve and maximum instantaneous gradient across the pulmonary valve greater than 60 mmHg or mean gradient greater than 40 mmHg, and in symptomatic patients with instantaneous gradient greater than 50 mmHg and mean gradient greater than 30 mmHg.[8]

Patients requiring balloon valvuloplasty as a palliative treatment for cyanosis and those with large defects in the interventricular septum were excluded as were those having dysplastic pulmonary valve and the pulmonary annulus less than 15 mm (in view of non availability of Inoue balloon catheter less than 22 mm). Patients with grade III or more Pulmonary regurgitation were also excluded from this study.

The degree of severity of the pulmonary valve stenosis as well as the pulmonary subvalvular obstruction was assessed and quantified with continuous wave Doppler. The presence and intensity of pulmonary regurgitation were assessed through colour flow mapping. The quantification was performed using the ratio between the width of the jet in its origin and the diameter of the pulmonary ring obtained in the parasternal short axis, considering that the values $\leq$10%, 11–25%, 26–50%, and >50% indicated degrees of regurgitation from I to IV respectively.[9]

2.2. Definitions

The procedure was deemed technically successful if the Inoue balloon could be advanced across the right ventricular outflow tract (RVOT) and dilatation at the orifice was achieved.

Failure was defined on the basis of lack of abolition of “waist” and angiographic non-relief of stenosis even after >2 incremental balloon dilatation and BAR above 1.4.

The patients were retrospectively divided into Group A (optimal immediate result; PSG $<$ 36 mmHg) and Group B (suboptimal immediate result; PSG $\geq$ 36 mmHg) and natural history of patients in both groups was studied.[10]

The efficacy of pulmonary valvuloplasty comprised the cases in which immediate success occurred or those in which, despite lack of immediate success, a later reduction was observed in the maximum instantaneous residual gradient to values $<$36 mmHg in subsequent Doppler echocardiographic studies.

Restenosis was defined as a new elevation on follow-up in the trans-valvular gradient to levels $\geq$ 36 mmHg after effective valvuloplasty.[10]

We prescribed beta blockers as per standard protocol for 3 months in all patients having suboptimal results.

2.3. Procedure

All patients were taken for BPV under conscious sedation with prior informed consent. As per standard protocol, intravenous heparin was given at a total dose of 100 U/kg after sheath insertion. A 5F right femoral arterial access was obtained for pressure monitoring. A standard diagnostic right heart catheterisation to include RV and PA pressure was performed. Right ventriculography in the left lateral view was done using an NIH catheter (Bard Inc., Billerica, MA) of appropriate size. This (Fig. S1A) helped in assessing the pulmonary annulus, the presence of systolic doming and ruling out sub-valvular obstruction. The pulmonary annulus diameter was measured from hinge to hinge during systole.

A 5F Judkins Right (JR) catheter was then delivered into the right heart over a 0.032 “double length angled tip guide wire (Fig. S1B) and placed distal to the stenotic pulmonary valve. The JR catheter was then exchanged over the wire with an 8F Mullins dilator (Cook Medical, Bloomington, IN, USA). A 270 cm, 0.025″ floppy-tipped stainless steel (Springer) guide wire (with the coiled end straightened as much as possible) was anchored distally in the dilated PA over the Mullins dilator, followed by removal of the dilator (Fig. S1C). A 14F dilator, part of the Inoue balloon catheter system, was used to dilate the venous groin access for facilitating passage of the balloon catheter.

A 12F Inoue balloon catheter (Toray Industries, Inc., Houston, TX) was prepared, with its balloon segment made air-free, stretched and slenderised by insertion of 18G silver metal tube. The catheter was inserted over the guide wire into the right femoral vein without use of a sheath and advanced into the right atrium and then into the RV. On reaching the level of RVOT, the metal tube was removed (de-slenderised), allowing the balloon to resume its more flexible natural shape. The catheter balloon was then manoeuvred across the stenotic valve with slight clockwise torque to facilitate easy crossing. It was positioned in the main pulmonary artery with the guide-wire firmly held in place (Fig. S1D and E). The distal half of the balloon was inflated with diluted contrast agent (dilution, 1:4). Initial inflation was performed with a balloon size 1–2 mm less than its maximal capacity. While the floppy tipped guide-wire was stabilised, the catheter was pulled back until the middle portion of the balloon was positioned just across the pulmonic valve (Fig. S1F). The balloon was fully inflated within 3–5 s and then quickly deflated. Abolition of the balloon “waist” was used as the endpoint (Fig. S1G and H). Repeat inflations with increased balloon diameters (0.5 ml increments) were performed until the waist was abolished. The deflated balloon was then removed while keeping the guidewire in the PA. The guidewire permitted repositioning of a Multi-Track Angio (Bonhoeffer) catheter (MAP Medical, North Lawrence, NY 12967) into the distal pulmonary artery for pull-back pressure measurement
(Fig. S1I). The same catheter was used for angiography (Fig. S1J) to assess leaflet mobility, iatrogenic injury to pulmonary or tricuspid valve, PA dissection and infundibular spasm.

After successful dilatation, angiography revealed an increase in the systolic excursion with relief in doming of the leaflets, and an increase in the width of the jet across the valve. Following BPV, all catheters were removed and hemostasis was secured by either manual compression or figure of eight subcutaneous linen suture at the puncture site.

After the procedure, all patients were transferred to the recovery facility and administered aspirin 3 mg/kg per day for six months. Transthoracic echocardiography (TTE) and electrocardiography were performed prior to discharge and patients were routinely assessed at one month after the procedure and yearly thereafter.

2.4. Statistical analysis

All data is presented as mean ± standard deviation for continuous variables and as proportions for categorical variables. SPSS version 20.0 (SPSS. Inc.) was used to perform statistical analysis. Continuous variables were analysed using student *t* test. All *p* values were two sided and $p < 0.05$ was considered as significant.

3. Results

3.1. Patient characteristics

Thirty-two patients aged 8–54 years (23.63 ± 11.45 years), underwent BPV, including 13 male and 19 female patients. The baseline characteristics of patients are summarised in Table S1. Two patients had small ostium secundum atrial septal defect (ASD), 3 had tiny patent ductus arteriosus and another had a small restrictive apical ventricular septal defect. Two patients were detected in their third trimester of pregnancy of whom one had associated moderate sized ostium secundum ASD.

In our study, most patients were symptomatic with complaints of effort intolerance or shortness of breath (78.13%). Two patient had syncopal episodes while three had symptoms of right heart failure with pedal oedema.

Two patients presented with restenosis after prior BPV. One of them had rheumatic involvement of both atrioventricular valves in addition to congenital pulmonary stenosis and had undergone BPV at 5 years of age. This patient presented with severe stenosis of both tricuspid and pulmonary valves at the age of 35 years and was taken up for relief of both valves in the same setting. The other patient was known case of isolated pulmonary stenosis and had undergone BPV 20 years back. She presented with multiple episodes of fast regular palpitations and was subjected to BPV along with electrophysiological study.

3.2. Haemodynamic results

3.2.1. Immediate results

The Inoue balloon catheter could be advanced with ease across the RVOT and dilatation at the orifice was achieved in all patients. All patients had typically a “dome-shaped” pulmonary valve, post-stenotic dilatation of the main pulmonary artery and marked trabeculation of RV on right ventricular angiography. The mean annular size and final balloon-to-annulus ratio was 18.79 ± 2.19 mm and 1.23 ± 0.11, respectively. The mean intra-balloon pressure was 2.6 ± 0.4 atm.

The RV systolic pressure decreased from 121.6 ± 42.4 to 61.2 ± 24.5 mmHg immediately post BPV. The pulmonary valvular peak to peak gradient was reduced from 100.9 ± 43.3 to 36.4 ± 22.5 mmHg with significant abolition of valvular gradient (<36 mmHg) in 20 patients. Both the redo-procedures were deemed as failures after more than 2 incremental balloon dilatation could not relieve the “waist”.

Twenty patients (80.5%, defined as Group A) showed optimal immediate results (immediate postoperative PSG <36 mmHg). The mean postoperative PSG of these patients was 22.7 ± 9.49 mmHg. The remaining 12 cases (19.5%, defined as Group B) had suboptimal immediate results (immediate postoperative PSG ≥36 mmHg), and their mean postoperative PSG was 59.33 ± 18.75 mmHg. In 10 of these patients infundibular spasm was noted either on angiogram or pullback gradients.

The difference between the two groups in the initial RV systolic pressure and peak systolic gradient was statistically significant ($p < 0.001$) [Table S2]. No significant difference between the 2 groups in regard to age, BAR and degree of reduction in the peak-to-peak pulmonary trans-valvular gradient was observed (Table S2). In none of Group B patients there was a drop in systemic pressure requiring inotropic support. There was no difference in post-procedural course and functional outcomes between the two groups.

3.3. Complications

Apart from infrequent ventricular premature beats, none of the patient experienced significant arrhythmic events. There was no episode of dizziness or syncope, stroke and hypotension during inflation. Trauma to the RV outflow tract or other cardiac structures did not occur in any patient. Post procedure, one patient developed deep venous thrombosis (DVT) extending to the common iliac vein. She was administered anticoagulation therapy and responded well with no evidence of DVT on last follow-up. All other patients were discharged the following day.

Increase in grade of PR by 1 grade was noted in 17 patients (53.13%) after BPV, however none of the patient had moderate or severe grade of PR. None of the patients developed significant tricuspid regurgitation.

3.4. Intermediate term results

A total of 23 of the 32 patients were available for follow-up in our study. Clinical and echocardiographic follow-up 0.25 to 5 years (mean, 2.75 years) was done to assess outcomes (survival, symptoms and need for a second intervention).

The acute haemodynamic benefits of BPV in our patients were maintained in the patients reassessed during intermediate-term follow-up. There was persistent and continued improvement after the procedure. In all the studied patients, there was no direct evidence of pulmonary valvular restenosis by repeat Echocardiography at a mean of 2.75 (Range 0.25–5) years. At the time of last follow-up, all patients were in NYHA class I except one adult in NYHA class II. The RV function was well maintained with tricuspid annular plane systolic excursion (TAPSE) of 22.71 ± 1.49 mm, as measured by M-mode of TTE.

Fourteen patients from Group A and 9 of Group B were reassessed on follow-up. The echocardiographically estimated peak instantaneous gradient across the pulmonary valve, was 18.67 ± 9.79 mmHg in patients of Group A and 23.6 ± 2.51 mmHg in patients of Group B (Fig. S2). There was a spontaneous reduction in peak instantaneous gradients to <36 mmHg in all followed up patients of Group B, thus increasing the efficacy of procedure on intermediate term follow-up. This indicated that irrespective of the magnitude of post-procedural fall in gradients, intermediate term results did not differ and were optimal in both groups (p NS) (Fig. S2). Doppler examination at follow-up revealed no significant increase in PR in any of the patients.

4. Discussion

Stenosis of the pulmonary valve is one of the more common forms of congenital heart disease. It needs adequate treatment in different age groups. The percutaneous dilation of the pulmonary valve with a balloon is currently considered the therapeutic modality of choice for the treatment of pulmonary valve stenosis in any age group and any valvular morphology.[8] Although the

percutaneous pulmonary valvuloplasty technique has undergone few changes over the years, there have been significant refinements in the hardware available for the procedure. The experience with Inoue balloon catheter technique for BPV is less described in literature. It is an attractive alternative to fixed size balloon techniques with added advantage of procedural ease.

Our study confirmed excellent outcomes with Inoue balloon technique in adult patients of PS. The valve was relieved in all but two patients. We encountered a late decrease in PSG across the pulmonary valve which increased the efficacy of the procedure over time. The appropriate BAR helped to alleviate complications like PR.

4.1. Safety, efficacy, and mid-term results

In this study, BPV using stepwise dilation technique with the Inoue size-adjustable balloon catheter was found to be feasible, safe, and efficacious. Furthermore, the beneficial effects of BPV were well maintained during follow-up, for as long as 5 years after the procedure.

Trans-catheter BPV of asymptomatic patients with isolated PS was has been controversial.[11–13] In developing countries, The chances of inadequate or late follow-up are not insignificant – hence it would seem prudent to perform the procedure even in asymptomatic patients with significant trans-valvular gradients. Indeed, three patients in the present study had symptoms of RV failure. The rationale for BPV includes not only the relief of symptoms but also prevention of secondary changes in the RV and progression to more severe degrees of stenosis.[13] The patients who had persisting gradients (>36 mmHg) (Group B) immediately after percutaneous dilation showed significantly greater initial RV-PA gradients and RVSP than those who obtained immediate success. However the RV-PA gradients were reduced to similar degree in both groups (Table S2), signifying that earlier intervention would result in a lower residual systolic gradient, with a consequent decrease in the occurrence of symptoms and of right ventricular hypertrophy in the long run.

Nine out of 12 patients in Group B were available for follow-up. The PSG decreased spontaneously to <36 mmHg in these patients. This phenomenon was observed in previous studies too.[13,15]

The efficacy of pulmonary balloon valvuloplasty is underestimated when only the immediate results are considered. This occurs due to a regression in the infundibular obstruction, considered a dynamic process that ebbs after a variable period of time and is similar to that observed after surgical valvotomy.[16] It is unclear whether infundibular stenosis is due to subvalvular muscular hypertrophy that subsequently resolves after successful treatment of the valvular stenosis or to infundibular spasm.[17] Some studies recommend the use of beta-blockers for patients after valvuloplasty,[18] We prescribed oral Propranolol routinely for three months to all patients after BPV with residual gradients deemed secondary to infundibular hypertrophy secondary to PS.

4.2. Comparison with the fixed-size balloon technique

A wide variety of balloon catheters are available and can be used to successfully treat pulmonary valve stenosis. The success of BPV depends on the ability of the selected balloon to achieve stable and complete inflation.[19] Rao et al. have suggested to choose a low profile balloon capable of advancing through the smallest possible vascular access in smaller patients whereas a balloon with higher rated burst pressure in adults.

The Tyshak series of balloons (NuMed, Hopkintown, NY) like Tyshak, Tyshak II and Tyshak mini have been designed for balloon valvuloplasty and ongoing modifications have been made in order to reduce the profile of the balloon catheter, while maintaining the resistance to balloon rupture. In adult patients where smaller vascular access size is less critical, there are a wide array of balloons with higher-rated burst pressure that have been developed, including the Z-med balloon series (NuMed), Diamond, Ultrathin, and XXL balloons (Boston Scientific, Natick, MA), Maxi-LD, Opta Pro, and Powerflex (Cordis Endovascular, Warren, NJ), and Marshal balloons (Meditech, Watertown, MA). The Nucleus balloon (NuMed) is designed to inflate to a "barbell" shape similar to an Inoue balloon. However, there are currently no published reports of the use of this balloon for pulmonary valve dilation.[19]

Double balloon technique is used in case of larger annular size with non availability of appropriate single balloon. It decreases the risk of hypotension during inflation due to a continuous flow between the balloons during inflation. On the other side it may prolong the procedure time and requires extra venous access. Studies have suggested an equal efficacy when comparing double balloon technique to single balloon at similar balloon/annulus ratio.[3,20]

Liu et al.[21] have shown that adults can be treated with BPV using the Inoue balloon with encouraging immediate and long-term follow-up results that are similar to those in children using the single balloon.

The Inoue balloon catheter technique is being used by us both for the ease of its use and easy availability of the balloon in our setup, whereas the fixed balloon technique used in 15 subjects during the study period so far in our institute has shown the known complications of Melon seeding (Video 1), rupturing[2] and in odd cases prolonged procedural time due to multiple exchanges in-between serial inflation. In 3 patients, the procedure was switched from fixed single balloon to Inoue balloon technique as the previous method was ineffective with significant slippage distally into pulmonary artery without abolition of waist ('ping-pong' or 'melon-seeding' effect).

The Inoue balloon catheter can be advanced freely in a relatively simpler RV inflow and outflow anatomy. However, in patients with "difficult-to-track" RV anatomy (severe tricuspid regurgitation with right atrial enlargement), the standard technique is limited by the rigidity of the metal stylet and also by inadequate support of the 0.025 "guidewire for tracking the Inoue catheter across the pulmonary valve. In two such cases the Inoue catheter (without the metal stylet) was slenderised over a 0.035" Amplatz superstiff guidewire (Cook Medical, Bloomington, IN), and tracked across the pulmonary valve.

4.3. Balloon sizing and pressure

Using an appropriate ratio of balloon to pulmonary valve hinge point diameter (BAR) is shown to optimise the chance of long-term success. The currently recommended ratio is 1.2–1.25.[19] Such smaller balloons are likely to result in good relief of pulmonary valve obstruction while at the same time may help to prevent significant pulmonary insufficiency at late follow-up. In the present study, we chose the appropriate balloon size on the basis of echocardiographic and angiographic measurements of the valve annulus The appropriate BAR was central in optimising the result and preventing the occurrence of pulmonary regurgitation in the study population.

In our study, the disappearance of the "waisting" of the balloon was noted even at 2 atm of pressure (mean 2.6 ± 0.4 atm) with resultant successful valvuloplasty. Rao et al.[17] have suggested to perform valvuloplasty sequentially at 3, 4, and 5 atm of pressure inflation. Yeager et al.[22] observed that pressures much higher than those required to abolish waisting of the balloon offer no advantage as the balloons maintain a relatively uniform diameter even at high pressures. High intra-balloon pressure may increase the chance of balloon rupture with the consequent problems.

4.4. Complications

We did not encounter any sustained arrhythmia, or haemodynaic compromise during the procedure. The incidence of residual pulmonary regurgitation (PR) after BPV in the most published series ranged from 40 to 90%.[10,23–25] Residual PR is usually of small magnitude after successful percutaneous dilation.[26] Its occurrence after the procedure may be explained by the fact that the mechanism of valvular opening through the use of balloon catheters consists of commissural separation, rupture, or even avulsion of the leaflets.[27]

The VACA study,[10] incriminated the BAR greater than 1.4, and complex valvular morphology due to a previous surgical valvotomy or the presence of valvular dysplasia for moderate pulmonary insufficiency. Rupture of the right ventricular outflow tract has been observed to be the major fatal complication of BPV occurring mostly in neonates or infants with critical pulmonary stenosis and hypoplastic pulmonary valve.[10] However, this complication seems to be extremely rare in adults.[7,28]

Previous experiences have shown that once successful dilatation is achieved, the chances of restenosis are very small.[11,29,30] In the present study, no patient had a pulmonary valve restenosis during the mid-term follow-up period of 5 yrs. Gradients at last follow-up were not significantly different from that obtained immediately after BPV in the group with immediate optimal result (Group A) whereas the gradients had decreased substantially in the group with suboptimal immediate results (Group B).

4.5. Limitation of the study

The present series is limited by our use of simple clinical examination and Doppler echocardiography to assess patients at follow-up. Other series have also used repeat cardiac catheterization in assessing follow-up pulmonary valve diameters and pressures. However, we feel that our use of simple clinical criteria is in keeping with current practice and avoids the requirement for repeat invasive procedures. The use of Doppler echocardiography allows the reliable and serial assessment of the stenotic lesion by determining the gradient through the pulmonary valve in any age group, which enables one to follow the natural history of the disease.[31–33] The second limitation is the relatively small patient population. The data in this study only applies to isolated PS and cannot be extended to patients with associated complex congenital lesions. These patients may have differences in clinical outcomes and procedural success. We did not directly compare the Inoue balloon catheter technique directly with fixed balloon technique in the present study.

5. Conclusions

BPV is currently considered the therapeutic modality of choice for the treatment of PS. But limited information is available on the selection of balloon techniques in adolescent and adults, particularly with regard to follow-up results. The present study confirmed excellent safety and favourable early and mid-term outcomes for BPV for isolated PS in adolescents and adults using the Inoue balloon catheter. Thus Percutaneous Inoue balloon technique is an attractive alternative for adolescents and adults with isolated PS and large annuli when performed by operators experienced with the Inoue balloon catheter.

Financial statement

No grants, contracts, and other forms of financial support received for this article.

Conflicts of interest

The authors have none to declare.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ihj.2016.11.316.

References

1. Marelli AJ, Mackie AS, Ionescu-Ittu R, Rahme E, Pilote L. Congenital heart disease in the general population: changing prevalence and age distribution. *Circulation*. 2007;115:163–172.
2. Kan JS, White Jr. RIJr., Mitchell SE, Anderson JH, Gardner TJ. Percutaneous balloon valvuloplasty: a new method for treating congenital pulmonary-valve stenosis. *N Engl J Med*. 1982;307:540–542.
3. Rao PS. Balloon pulmonary valvuloplasty: a review. *Clin Cardiol*. 1989;12 (2):55–74.
4. Inoue K, Owaki T, Nakamura T, Kitamura F, Miyamoto N. Clinical application of transvenous mitral com-missurotomy by a new balloon catheter. *J Thorac Cardiovasc Surg*. 1984;87:394–402.
5. Lau KW, Hung JS, Wu JJ, Chem MS, Yeh KH, Fu M. Pulmonary valvuloplasty in adults using the lnoue balloon catheter. *Cardiovasc Diagn*. 1993;29:99–104.
6. Bahl VK, Chandra S, Wasir HS. Pulmonary valvuloplasty using Inoue balloon catheter. *Int J Cardiol*. 1994;45(2):141–143.
7. Chen CR, Cheng TO, Huang T, et al. Percutaneous balloon valvuloplasty for pulmonic stenosis in adolescents and adults. *N Engl J Med*. 1996;335:21–25.
8. Warnes CA, Williams RG, Bashore TM, et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing committee to develop guidelines on the management of adults with congenital heart disease). *Circulation*. 2008;118:e714–e833.
9. Cooper JW, Nanda NC, Philipot EF. Evaluation of valvular regurgitation by color Doppler. *J Am Soc Echocardiogr*. 1989;2:56–66.
10. McCrindle BW. Independent predictors of long-term results after balloon pulmonary valvuloplasty. *Circulation*. 1994;89:1751–1759 (25).
11. Rao PS. Long term follow up results after balloon dilatation of pulmonic stenosis, aortic stenosis, and coarctation of the aorta: a review. *Prog Cardiovasc Dis*. 1999;42:59–74.
12. Rao PS. Indications for balloon pulmonary valvuloplasty. *Am Heart J*. 1988;116 (6 Pt 1):1661–1662.
13. Nadas AS. Pulmonic stenosis – indications for surgery in children and adults. *N Engl J Med*. 1972;287(23):1196–1197.
15. Parent JJ, Hoyer MH. Delayed success of balloon dilation for coexisting pulmonary valve stenosis and sinotubular narrowing. *Congenit Heart Dis*. 2014;9:216–220 Epub 2013 June 27.
16. Earing MG, Connolly HM, Dearani JA, Ammash NM, Grogan M, Warnes CA. Long-term follow-up of patients after surgical treatment for isolated pulmonary valve stenosis. *Mayo Clin Proc*. 2005;80:871–876.
17. Lee ML, Peng JW, Tu GJ, Chen SY, Lee JY, Chang SL. Major determinants and long-term outcomes of successful balloon dilatation for the pediatric patients with isolated native valvular pulmonary stenosis: a 10-year institutional experience. *Yonsei Med J*. 2008;49:416–421.
18. Khambatta HJ, Velado M, Gaffney JW, Schechter WS, Casta A. Management of right ventricular outflow tract reactivity following pulmonary valve dilatation under general anesthesia: experience of a medical mission. *Paediatr Anaesth*. 2006;16:1087–1089.
19. Rao PS. Percutaneous balloon pulmonary valvuloplasty: state of the art. *Catheter Cardiovasc Interv*. 2007;69:747–763.
20. Rao PS, Fawzy ME. Double balloon technique for percutaneous balloon pulmonary valvuloplasty: comparison with single balloon technique. *J Interv Cardiol*. 1988;1:257–262.
21. Liu S, Xu X, Liu G, Ding X, Zhao X, Qin Y. Comparison of immediate and long-term results between the single balloon and Inoue balloon techniques for percutaneous pulmonary valvuloplasty. *Heart Lung Circ*. 2015;24(January (1)):40–4510.1016/j.hlc.2014.05.020.
22. Yeager SB. Occlusion time and inflation pressure in pulmonary valvuloplasty (letter). *Am J Cardiol*. 1985;55:619.
23. Berman Jr. WJr., Fripp RR, Raiser BD, Yabek SM. Significant pulmonary valve incompetence following oversize balloon pulmonary valvuloplasty in small infants: a long-term follow-up study. *Catheter Cardiovasc Interv*. 1999;48:61–65.
24. Abu Haweleh A, Hakim F. Balloon pulmonary valvuloplasty in children: Jordanian experience. *J Saudi Heart J*. 2003;15:31–34.
25. Garty Y, Veldtman G, Lee K, Benson L. Late outcomes after pulmonary valve balloon dilatation in neonates, infants and children. *J Invasive Cardiol*. 2005;17:318–322.
26. Rao PS, Fawzy ME, Solymar L, Mardini MK. Long-term results of balloon pulmonary valvuloplasty of valvar pulmonic stenosis. *Am Heart J*. 1988;115:1291–1296.
27. Walls JT, Lababidi Z, Curtis JJ. Morphologic effects of percutaneous balloon pulmonary valvuloplasty. *South Med J*. 1987;80:475–478.

28. Karagoz T, Asoh K, Hickey E, et al. Balloon dilation of pulmonary valve stenosis in infants less than 3 kg: a 20-year experience. *Catheter Cardiovasc Interv*. 2009;74:753–761.
29. Rao PS, Galal O, Patnana M, Buck SH, Wilson AD. Results of three to 10 year follow-up of balloon dilatation of the pulmonary valve. *Heart*. 1998;80:591–595.
30. Qian X, Qian Y, Zhou Y, Yang X. Percutaneous pulmonary balloon valvuloplasty provides good long-term outcomes in adults with pulmonary valve stenosis. *J Invasive Cardiol*. 2015; Epub ahead of print.
31. Gielen H, Daniëls O, van Lier H. Natural history of congenital pulmonary valvar stenosis: an echo and Doppler cardiographic study. *Cardiol Young*. 1999;9:129–135.
32. Rowland DG, Hammill WW, Allen HD, Gutgesell UP. Natural course of isolated pulmonary valve stenosis in infants and children utilizing Doppler echocardiography. *Am J Cardiol*. 1997;79:344–349.
33. Vermilion RP, Snider R, Bengur AR, Meliones JN. Long-term assessment of right ventricular diastolic filing in patients with pulmonic valve stenosis successfully treated in childhood. *Am J Cardiol*. 1991;68:648–652.

Further reading

14. Nugent EW, Freedom RM, Nora JJ, Ellison RC, Rowe RD, Nadas AS. Clinical course in pulmonary stenosis. *Circulation*. 1977;56(suppl 1):I38–47.