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A retrograde approach for transcatheter valvotomy procedure in infants with pulmonary atresia intact ventricular septum (PA-IVS): retrograde versus antegrade approach

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Abstract

Introduction: This study evaluates the retrograde approach compared to the antegrade approach in infants with PA-IVS who underwent transcatheter pulmonary valvotomy procedure at National Cardiovascular Center Harapan Kita, Jakarta, Indonesia. *Material and method:* This is a single-centre retrospective study conducted from January 2017 to June 2019 consisting of infants undergoing transcatheter pulmonary valvotomy procedures from our centre. *Results:* Among 3733 records of cardiac catheter procedure in paediatric patients during the last 3 years, there were 12 subjects with PA-IVS, where five subjects were done by antegrade approach and seven by retrograde approach. The retrograde approach is shown to excel the antegrade approach in terms of procedural time by 58.64 minutes (CI 95 % 32.97–84.29, $p = 0.008$) and PA-RV crossing time by 27 minutes (CI 95 % 14.01–39.99, $p = 0.02$). There was no significant difference in contrast used (120.23 ± 25.77 versus 150.27 ± 39.26 ml/BSA, $p = 0.518$), and right ventricle to pulmonary artery systolic pressure gradient after valvotomy (39.571 ± 5.814 versus 53.52 ± 29.15, $p = 0.329$) between the retrograde and the antegrade approach. *Conclusion:* The retrograde approach offered shorter procedural time and comparably satisfying results than the antegrade approach. The shorter procedural time was preferred due to the shorter duration of general anaesthesia, which may decrease the risk of neurodevelopmental deficits in the patient.

Pulmonary atresia with intact ventricular septum (PA-IVS) is one of the critically congenital heart disease spectrum, which accounts for 3% (4–8 per 100,000 live births) of all CHD. Besides, it is the third most common spectrum of cyanotic CHD.[1] It is considered a critical congenital heart defect due to the cardiac malformation/s, which manifests with low oxygen saturation levels. Infants with critical congenital heart defect will eventually need urgent surgical or catheter-based intervention during the first year of life.[2]

Percutaneous pulmonary valvotomy is one of the possible interventions in infants with PA-IVS. They fulfill the criteria for biventricular circulation (adequate right ventricular size, no right ventricular coronary dependent circulation (RVDCC), tricuspid valve Z score > -2, functionally tripartite right ventricle, and no more than moderate tricuspid regurgitation). The valvotomy procedure might be performed using stiff wire, laser, or radiofrequency energy followed by balloon dilatation. Although surgical repair may be a choice, its morbidity remains high, reaching a 1-year mortality rate of 52%.[3] Furthermore, a study by Alwi et al. proved the superiority of the radiofrequency valvotomy procedure and balloon dilatation compared to surgical valvotomy and BT shunt in patients with biventricular circulation PA-IVS. The former was proven to be more efficacious and safe.[4] Thus, percutaneous pulmonary valvotomy has become the treatment of choice. It has been more than three decades since Latson LA did the first valvotomy procedure in 1991, and the method has always been the same eversince.[3–7] Thus, we tried a different approach using a more direct approach which we called the retrograde approach and compared it with the usually used antegrade approach in terms of procedural time and other outcomes. Hopefully, this new method will prove to be a better alternative to the usual approach.

Method

Subject selection

A total of 12 consecutive patients with PA-IVS underwent transcatheter pulmonary valvotomy procedures at our institution from January 2017 to June 2019. We collected clinical data from the medical record and cath lab log report. Subjects who underwent transcatheter pulmonary valvotomy procedures using the usual approach (antegrade approach) and retrograde approach were included in this study. Incomplete data in any of the components for statistical analysis: procedural time, contrast used, and follow-up echocardiography evaluation will be excluded from the available data but will be analyzed for adverse event analysis.

Examination before procedure

Every new infant referred to our hospital underwent physical examination, chest X-ray, and transthoracic echocardiography was performed in every new infant referred to our hospital. Infants who were diagnosed with PA-IVS from transthoracic echocardiography were admitted and examined further for pre-intervention echocardiography study to evaluate the components of ventricle, tricuspid annulus "z" score, right ventricle sinusoid or coronary fistula as the sign of RVDCC, interatrial communication, the presence of ductus arteriosus, and branch of pulmonary artery anatomy. Patients who fulfill the following criteria were deemed suitable for biventricular circulation candidates: 1) Tricuspid valve Z score > -2[1,8]; 2) No severe tricuspid regurgitation; 3) Almost normal size or slightly hypoplastic right ventricle; 4) Tripartite right ventricle; and 5) non RVDCC.

Transcatheter valvotomy procedure

The decision to use the usual (antegrade) and retrograde approaches was based on the operator's preference and experience. All procedures were performed under general anaaesthesia, and prostaglandin E1 10 nanograms/kg/minute was given in a fully-equipped bi-plane catheterisation laboratory after consent was given from the parents or guardians.

Retrograde Approach or One-Access Intervention Approach

The right femoral artery was selected for vascular access, and a sheath was placed, followed by the administration of intra-arterial heparin at 100 units per body weight directly from the sheath. A 4F Pigtail catheter was inserted from the right femoral artery to the descending aorta, aortic arch, and ascending aorta using the guide of 0.035" J wire, followed by pressure recording and blood sampling for blood gas analysis. Aortography was done in the ascending aorta with lateral angulation to visualise the ductus arteriosus and right ventricle to pulmonary artery connection, exclude the presence of RVDCC and map the anatomical landmark for the valvotomy procedure. The 4F pigtail catheter was exchanged with a diagnostic or directly guiding catheter Judkins Right catheter, which was used to cross the ductus arteriosus to the pulmonary artery with the help of soft wire 0.035". Pulmonary arteriography (lateral view) was done to ensure the anatomical landmark of the atretic pulmonary valve for the valvotomy procedure. Valvotomy was done at the cusp of the semilunar pulmonary valve (edge of pulmonary valve) using the *bottom stiff-end* wire 0.014, which further ballooned gradually from sizes of 1.5 mm, 3 mm, and 8–10 mm.

Usual (antegrade) approach or Two-Access Intervention Approach

The right femoral vein and artery were punctured, and sheaths were placed at both access points. Intra-arterial heparin of 100 units per body weight was injected directly through the arterial sheath. A 4F Pigtail catheter was inserted from the right femoral artery to the descending aorta, aortic arch, and ascending aorta with a 0.035" J wire. Ascending aortography was done with lateral view to visualise ductus arteriosus excluding the presence of RVDCC and the atretic pulmonary valve. Meanwhile, a 4F or 5F Judkins Right catheter was inserted from the right femoral vein to the inferior vena cava, right atrium, right ventricle, and right ventricular outflow tract. Right ventriculography was done with lateral view to visualise the right ventricular outflow tract and exclude the presence of RVDCC. Perforation of the atretic pulmonary valve (valvotomy) was performed from the right ventricular outflow tract at the centre of the semilunar pulmonary valve using *bottom stiff-end* wire 0.014 (Fig 2). Balloon valvuloplasty was then conducted using coronary and Thysak balloons gradually from size 1.5 mm, 3 mm, and 8–10 mm.

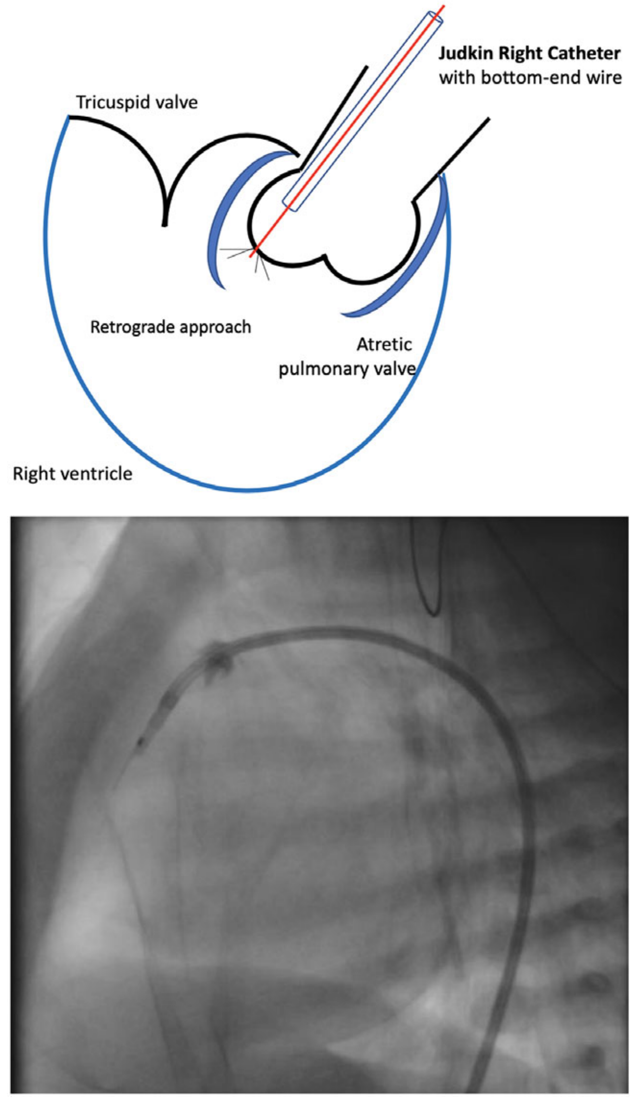

Figure 1. Upper image: Illustration of the retrograde approach; Bottom image: angiographic lateral view pulmonary valvotomy using the retrograde approach.

Outcome

This study's primary outcome was the procedural time, which was calculated from the first attempt of puncture to the end of the

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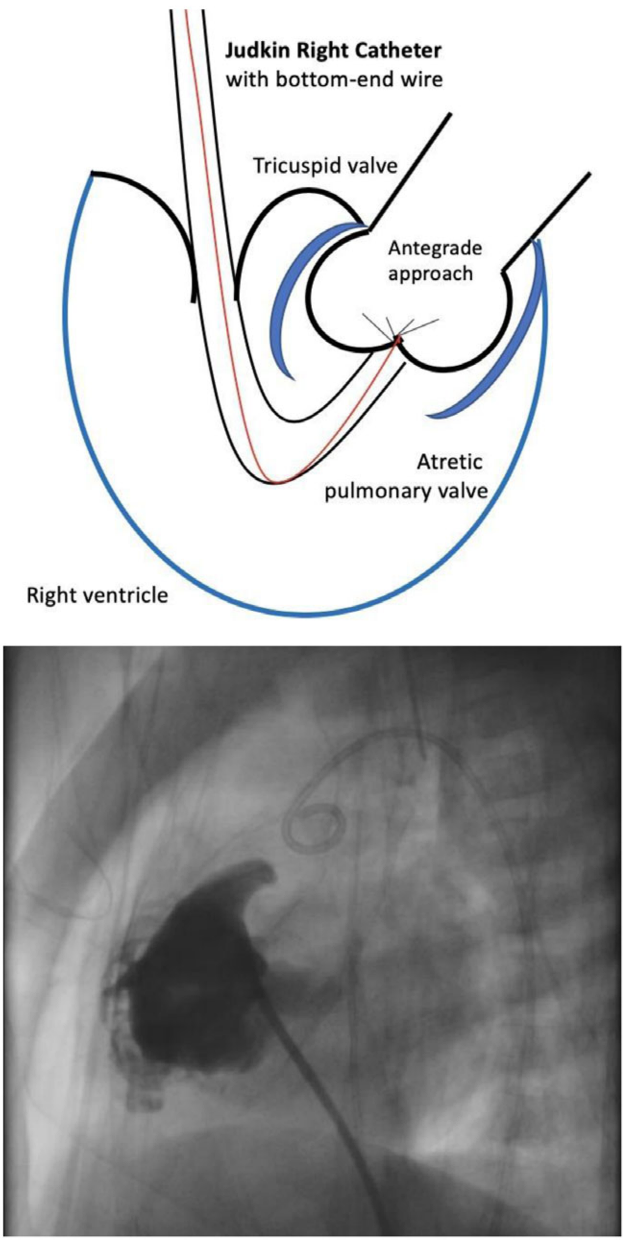

Figure 2. Upper image: Illustration of the usual (antegrade) approach; Bottom image: angiographic lateral view pulmonary valvotomy using the usual (antegrade) approach.

procedure as stated in the catheterisation log report. Meanwhile, the secondary outcomes were the pulmonary artery to right ventricle crossing time, the amount of contrast used per body surface area, right ventricle to pulmonary artery gradient systolic pressure gradient from transthoracic echocardiography directly after the procedure, peripheral oxygen saturation after the procedure, and the difference from before the procedure; and lastly the adverse event following the pulmonary valvotomy and ballooning procedure.

Result

Among 3733 records of cardiac catheterisation studies in paediatric patients during the last 3 years from January 2017 to June 2019, there were 12 infants with PA-IVS undergoing pulmonary valvotomy. Five subjects were done ante, and seven by *retrograde* approach. All data were obtained from the medical record and catheterisation log report. One patient switched from the usual (antegrade) approach due to being unable to position the tip of the catheter in the pulmonary valve. No patients were excluded from the search procedure. As shown in Table 1, most subjects were male (58%) with no statistical differences in age (43.28 ± 9.06 versus 71 ± 35.12, $p = 0.483$) and body surface area (0.231 ± 0.07 versus 0.276 ± 0.35, $p = 0.278$) between the *retrograde* and antegrade approaches. Echocardiography measurements of the tricuspid valve z-score of all subjects were above −2.0, mild hypoplastic tripartite right ventricle with no evidence of sinusoid or coronary fistula as the sign of RVDCC. Although the tricuspid valve z-score in the retrograde approach group was slightly lower than the usual (antegrade) group, it was not statistically significant (-0.12 ± 0.19 versus 0.57 ± 0.50, $p = 0.249$).

In terms of intra and post-procedure outcomes (Table 2), we found no significant differences in contrast used (120.23 ± 25.77 versus 150.27 ± 39.26 ml/BSA, $p = 0.518$), right ventricle-pulmonary artery gradient post valvotomy (39.571 ± 5.814 versus 53.52 ± 29.15, $p = 0.329$), and oxygen saturation pre (74.86 ± 2.35 versus 64.4 ± 6.12, $p = 0.102$) and post (88 ± 1.46 versus 87.6 ± 1.72, $p = 0.863$) procedure between the retrograde approach and the usual (antegrade) approach. Meanwhile, the retrograde approach was shown to be faster than the antegrade approach in terms of procedural time by 58.64 minutes (CI 95 % 32.97–84.29, $p = 0.008$) and PA-RV crossing time by 27 minutes (CI 95 % 14.01–39.99, $p = 0.02$).

The sheath size used for vein access for the usual (antegrade) approach varied between 4F and 5F; meanwhile, the 4F sheath size was used for arterial access in the same group of subjects. For the retrograde approach, which only used one intervention access (arterial access), most of the procedures used a 5F sheath size (71%). The type of bottom stiff-end wire for valve perforation (valvotomy) was used based on the availability of wire during the procedure, ranging from Run-through NS Floppy, Hi-Torque Family, Sion Blue, Gaia Third, or Conquest pro (Table 1). Adverse events found during the procedure were supraventricular tachycardia in one patient, and cardiac tamponade that ended in cardiac arrest in one patient resuscitated during the usual (antegrade) approach procedure. There were no cardiac or vascular complications during and after the procedure in the retrograde procedure.

Discussion

Latson did the first non-surgical treatment for PA-IVS using transcatheter valvotomy in 1991. It was first done in a 5-hour-old 3.2 kg neonate with PA-IVS and mildly hypoplastic tripartite right ventricle using the stiff end of the wire.[7]

Radiofrequency or stiff wire was used at the time to penetrate coronary chronic total occlusion.[3–6,9,10] Thus far, the usual (antegrade) approach or two-access approach is the primarily used technique for valvotomy procedure.

Although considered a safe procedure, the usual (antegrade) approach or two-access approach is time-consuming, which would prolong the procedural time, as proven in our study. Longer procedural time will eventually cause longer turnover time, delaying the next procedure in line.[11] Another issue is hypothermia in infants, which can quickly develop in a catheterisation laboratory cold environment. These issues became a problem because no integrated infant warmer was available in our cath lab. Thus, hypothermia

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Table 1. Baseline characteristic of the study population

Subject	Gender	Age at procedure (Days)	Type of approach	Sheath size*	Bottom-end wire for valvotomy	Complication
Patient 1	Male	13	Antegrade	v = 5F; a = 4F	Conquest pro	Supraventricular Tachycardia
Patient 2	Male	100	Antegrade	v = 5F; a = 4F	Sion Blue	
Patient 3	Male	12	Antegrade	v = 4F; a = 4F	J Wire	
Patient 4	Male	196	Antegrade	v = 5F; a = 4F	Hi-Torque Family	
Patient 5	Male	34	Antegrade	v = 4F; a = 4F	Conquest pro	Cardiac Tamponade, Cardiac arrest
Patient 6	Female	33	Retrograde	a = 4F	Gaia Third	
Patient 7	Female	63	Retrograde	a = 5F	Sion Blue	
Patient 8	Male	11	Retrograde	a = 5F	Sion Blue Guide wire	
Patient9	Female	34	Retrograde	a = 4F	Runthrough NS Floppy	
Patient 10	Female	83	Retrograde	a = 5F	Conquest pro	
Patient 11	Male	29	Antegrade switch to Retrograde	v = 5F; a = 4F switch to a = 5F	Conquest pro	
Patient 12	Female	50	Retrograde	a = 5F	Sion Blue	

*v = vein; a = artery.

may delay recovery from anaesthesia and induce arrhythmia.[12,13] But, more importantly, the longer procedural time will affect the duration of general anaesthesia since the procedural time was more or less the same with the time patients were under general anaesthesia. The research has not been thoroughly published, but repeated and prolonged use of general anaesthesia in patients under 3 years of age may affect the development of children's brains.[14]

Meanwhile, the first randomised controlled equivalence trial by McCann ME et al. proved that under 1 hour of general anaesthesia in early infancy does not alter neurodevelopmental outcome.[15] Therefore, an approach with shorter procedural time should be preferred.

The reason behind the shorter procedural time in the retrograde approach was for several reasons: 1) Retrograde approach uses only one access, which is an arterial approach. RVDCC, which is the primary concern that can be missed during echocardiography, may be ruled out by aortogram.[16]

Two accesses (vein and arterial access) may take time and may cause haematoma due to multiple puncture attempts; 2) Retrograde approach use may hinder unnecessary bending of the catheter, which might affect its steerability for valvotomy purpose compared to the usual (antegrade) approach (Fig 2). These facts were proven by shorter PA-RV crossing time in the *retrograde* approach, and one patient was switched from antegrade to *retrograde* approach due to being unable to position the tip catheter in front of the pulmonary valve from the antegrade approach.

Compared with the antegrade approach, the retrograde approach does not need a special manoeuvre to place the tip of the catheter directly over the pulmonary artery cusp. Meanwhile, the approach from the antegrade requires the catheter to bend into the RV and do another bending to reach the cusp of the pulmonary artery.

Despite the faster procedural time and reaching a comparably satisfying result in the retrograde approach compared to the antegrade approach; however, the RV to PA systolic pressure gradient and peripheral oxygen saturation after the procedure were not significantly different (Table 1).

In terms of safety, contrast use was relatively lower in the retrograde approach than in the usual (antegrade) approach. However, the difference was not statistically significant. Besides, although no complications related to the procedure are found in the *cutting-edge* (Retrograde) approach, further studies might be needed to further safety analysis between the two approaches.

The unique feature of the retrograde approach is that the valvotomy procedures are done at the "edge" or the cusp of the semilunar valve, not at the centre of the pulmonary cusp as was done in the usual (antegrade) approach. Concern arose regarding the method of perforating the cusp that might end up with significant pulmonary regurgitation. However, our data showed that only one patient in each group experienced moderate pulmonary regurgitation post valvotomy and ballooning procedure. The reason might be due to fewer balloon dilatation procedures needed in retrograde compared to antegrade approach which was caused by easier balloon placement using the retrograde approach. Therefore, although the retrograde approach was prone to cause pulmonary regurgitation anatomically, it was compensated with fewer balloon dilatation procedures.

Conclusion

The retrograde approach offered shorter procedural time and more satisfying results than the usual (antegrade) approach. The shorter procedural time was preferred due to the shorter duration of general anaesthesia, which may decrease the risk of neurodevelopmental deficits in the patient.

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Table 2. Summary of retrograde and antegrade approach valvotomy procedure

		Retrograde approach n = 7	Antegrade approach n = 5	p value
Age (Day)		43.28 ± 9.06	71 ± 35.12	0.483
Body surface area (BSA)		0.231 ± 0.07	0.276 ± 0.35	0.278
Tricuspid valve Z-score		−0.12 ± 0.19	0.57 ± 0.50	0.249
Procedural time (minute)		68.57 ± 10.29	127.2 ± 15.37	**0.008**
PA to RV crossing time (minute)		37 ± 5.53	64 ± 7.46	**0.02**
Contrast (mL/BSA)		120.23 ± 25.77	150.27 ± 39.26	0.518
RV to PA systolic pressure gradient post procedure		39.571 ± 5.814	53.52 ± 29.15	0.303
Peripheral O_2 saturation before valvotomy		74.86 ± 2.35	64.4 ± 6.12	0.102
Peripheral O_2 saturation after valvotomy		88 ± 1.46	87.6 ± 1.72	0.863
PR after valvulotomy				
	No	2 (29%)	1 (20%)	
	Trivial	1 (14%)	1 (20%)	
	Mild	3 (43%)	2 (40%)	
	Moderate	1 (14%)	1 (20%)	

PR = pulmonary regurgitation; RV to PA = right ventricle to pulmonary artery; PA to RV = pulmonary artery to right ventricle.
Bold value indicate $p < 0.05$.

Limitation

There are several limitations to our study. *First*, the number of subjects was still small; therefore, this study may need to be validated with a more significant number of subjects. *Second*, the fluoroscopy time data was not obtained during the procedure. This variable should be noted and collected for future studies.

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Conflicts of interest. None.

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