Balloon pulmonary valvuloplasty in neonates with critical pulmonary stenosis: Jugular or femoral

Erick Hoetama, Radityo Prakoso, Poppy Surwianti Roebiono, Indriwanto Sakidjan, Yovi Kurniawati, Sisca Natalia Siagian, Olfi Lelya, Anna Ulfah Rahajoe, Ganesja Moelia Harimurti, Oktavia Lilyasari
Pediatric Cardiology and Congenital Heart Disease Division, National Cardiovascular Center Harapan Kita, Faculty of Medicine, Universitas Indonesia, Jakarta, Indonesia

ABSTRACT

Background: Critical pulmonary stenosis (PS) is one of the life-threatening congenital heart diseases which present during the neonatal period with cyanosis. Surgical valvotomy was once the procedure of choice for critical PS; however, balloon pulmonary valvuloplasty (BPV) has now become the standard treatment. Although the procedure is usually simple, crossing the pulmonary valve from the femoral vein can be difficult, especially when severe tricuspid regurgitation and right atrium dilatation are present. In such patients, the maneuver can be simplified by using the right internal jugular vein approach. However, many operators are reluctant to use this approach because of unfamiliarity with the technique, potential complications, and paucity of reports. Until now, there is no literature describing BPV using the transjugular approach in neonates, also none directly comparing the transfemoral and transjugular approaches.

Objective: We compared transjugular with the transfemoral approach in terms of procedure time and complications.

Materials and Methods: This was a retrospective cohort study. Participants were neonates with critical PS undergoing BPV in the National Cardiovascular Center Harapan Kita from 2013 to 2018.

Results: Of 15 neonates undergoing BPV, eight were done using the transjugular approach and seven using the femoral approach. Mean age and weight in both groups was similar. In all eight patients using transjugular approach, crossing the pulmonary valve was consistently quick and easy. The total procedural time, pulmonary crossing time, and fluoro time was significantly shorter using the transjugular approach (65 ± 8 vs. 108 ± 17.8 min, P < 0.05; 22 ± 3.1 vs. 45 ± 14.8 min, P < 0.01; 29 ± 13 vs. 67 ± 35 min, P < 0.05). There were no complications relating to vascular access. Moreover, the BPV procedure itself demonstrated comparable results in both groups.

Conclusion: BPV using the transjugular approach is safe and effective to relieve critical PS in neonates compared to the transfemoral approach.

Keywords: Balloon pulmonary valvuloplasty, critical pulmonary stenosis, neonate, transjugular
INTRODUCTION

Critical pulmonary stenosis (PS) is a life-threatening congenital heart disease which requires immediate treatment. Unlike older children with isolated PS, neonates with critical PS presents with severe cyanosis and the suprasystemic right ventricle (RV) pressure may result in RV dilatation and failure with severe tricuspid regurgitation (TR). Since the discovery of balloon pulmonary valvuloplasty (BPV), it has replaced surgical approach for relieving PS. Femoral vein is the most common venous access for BPV; however, crossing the pulmonary valve using this approach can be difficult, especially in the presence of severe TR and right chambers dilatation. This problem can be overcome by using transjugular approach, yet many operators are reluctant to use this method because of potential complications and lack of data reporting transjugular approach. Until now, there are only a few cases reported BPV using transjugular approach and none were performed in the neonate. There is also no literature directly compared between transjugular and transfemoral approach. Therefore, we aim to compare both approaches for BPV in neonates in terms of total procedural time and complications related to the vascular access.

MATERIALS AND METHODS

This study was single-center study, and data were collected from our institution medical record. Over a period of 6 years (2013–2018), there were 15 BPV performed for critical PS in neonates. Patients ranged in age between 1 and 28 days and in weight from 2.7 to 4.2 kg. Critical PS was defined as the right ventricular pressure ≥75% of the left ventricular pressure or a gradient >60–70 mmHg accompanied by severe cyanosis (oxygen saturation <70%–75%). A detailed clinical evaluation, electrocardiogram, chest X-ray, and Doppler echocardiography were performed in all these patients before the procedure. The selection criteria for the transjugular and transfemoral approach were based on operator’s preference and experience.

Transjugular approach procedure

For all cases, the BPV procedure was performed under general anesthesia. Continuous electrocardiographic monitoring was maintained. In each patient, we used the right internal jugular vein (IJV) for puncture site because it provides a more direct route to the heart. The patient’s head was turned opposite to the puncture site with shoulders slightly elevated. The puncture site was approximately midway between suprasternal notch and mastoid process, between the medial and lateral bellies of the sternocleidomastoid muscle. A needle was then inserted in the direction of the nipple on the punctured site at an angle 30°–40° caudal from vertical. After the IJV was successfully punctured, a guidewire was advanced to the right atrium under fluoroscopic visualization. The needle was removed and replaced by the appropriate size sheath (4F to 5F). After that, angiography of the pulmonary artery (PA) was performed to measure the diameter of the annulus. Valvuloplasty should be performed with a balloon approximately 1.2 times the annulus diameter. At the end of the procedure, hemostasis was achieved in all patients with firm hand pressure.

Statistical analysis

Continuous baseline variables are described as mean (standard deviation) and compared between groups using Student’s t-test. The reported P values are the results of two-sided tests. Values of P ≤ 0.05 are considered to be statistically significant. The IBM SPSS version 22.0 (IBM SPSS Statistics version 22.0, Armonk, NY: IBM Corp) was used for statistical analysis.

RESULTS

Table 1 summarizes the baseline characteristic of study participants, whereas Table 2 summarizes the details of BPV by both approaches. From 15 participants undergoing BPV, eight were done using the transjugular approach and seven others using the transfemoral approach. Mean age in the transjugular group is 9 ± 3.2 days and in transfemoral group is 19 ± 5.2 days, whereas mean weight is 3.2 kg in both groups. Most of the procedure in both groups were done using 5F sheath, and balloon size ranged from 3 mm to 12 mm. The BPV itself showed a very satisfying result, as can be seen from a significant improvement in parameters such as RV systolic pressure, RV-PA gradient, and oxygen saturation. Majority of patients had moderate-to-severe TR. Of the 15 patients, only six experienced procedure related events transient total atrioventricular block and right bundle branch block (three patients), transient sinus bradycardia (two patients), and transient supraventricular tachycardia (one patient). Five events occurred in the transjugular group and one event in the transfemoral group. These events occurred during attempts to cross the pulmonary valve with the balloon dilatation catheter or immediately after balloon dilatation, and all of them resolved completely. Furthermore, we found no complications at all regarding vascular access in the transjugular group, as well as the transfemoral group. Procedural time is counted from puncture time to last balloon dilatation. There is a significant reduction of total procedural time in the transjugular group compared to transfemoral group (65 ± 8 vs. 108 ± 17.8 min) with a mean difference 42 min (95% confidence interval [CI] 2.7–83.2). Further analysis also showed significant reduction in both PA crossing time (12 ± 3.1 vs. 35 ± 14.8 min, mean difference...
Table 1: Baseline characteristic of the study population

| Variables                          | Transjugular (n=8) | Femoral (n=7) | P  | Mean difference (95% CI) |
|------------------------------------|--------------------|---------------|----|-------------------------|
| Age (days)                         | 9±3.2              | 19±5.2        | >0.05 |                        |
| Weight (kg)                        | 3.2±1.5            | 3.2±0.8       | >0.05 |                        |
| RV pressure preBPV (mmHg)          | 71±10.3            | 79±10         | >0.05 |                        |
| RV pressure postBPV (mmHg)         | 32±3.9             | 42±6.3        | >0.05 |                        |
| RV-PA gradient preBPV (mmHg)       | 77±9.5             | 55±6.7        | >0.05 |                        |
| RV-PA gradient postBPV (mmHg)      | 26±7.5             | 16±4.7        | >0.05 |                        |
| SO2 preBPV (%)                     | 70±2               | 71±10.1       | >0.05 |                        |
| SO2 postBPV (%)                    | 90±1.1             | 91±1.8        | >0.05 |                        |
| Tricuspid regurgitation            |                    |               |     |                        |
| Mild                               | 2                  | 2             | >0.05 |                        |
| Moderate                           | 3                  | 3             |       |                        |
| Severe                             | 3                  | 3             |       |                        |
| Procedural time (min)              | 65±8               | 108±17.8      | <0.05 | 42 (2.7-83.2)           |
| PA crossing                        | 3±0.7              | 4±1.1         | 0.075 | 0.89 (~1.8-0.1)         |
| Fluoro time                        | 29±13              | 67±35         | <0.05 | 38 (9.0-67.4)           |

Complications regarding vascular access
- -

RV: Right ventricle, PA: Pulmonary artery, TV: Tricuspid valve, SO2: Oxygen saturation, BPV: Balloon pulmonary valvuloplasty, CI: Confidence interval

Table 2: Summary of transjugular and transfemoral approach

| Patient | Age (days) | Weight (kg) | Approach | Sheath size | Balloon type | Balloon size | Postdilatation complication | Echocardiography |
|---------|------------|-------------|----------|-------------|--------------|--------------|----------------------------|------------------|
| 1       | 28         | 2.9         | Jugular  | 5F          | Ryujin, Mini Thysak | 4.9          | -                          | Severe TR, dilated RA/RV |
| 2       | 3          | 3.5         | Jugular  | 4F          | Mini Tyshak   | 5.8          | Mild TR                    |                  |
| 3       | 1          | 2.7         | Jugular  | 5F          | Maverick, Mini Thysak | 3.9          | Transient TAVB, RBBB       | Moderate TR, dilated RA/RV |
| 4       | 3          | 3.6         | Jugular  | 4F          | Sprinter Legend, Mini Thysak | 4.0          | Transient RBBB             | Moderate TR, dilated RA/RV |
| 5       | 14         | 2.7         | Jugular  | 4F          | Mini Tyshak   | 5            | Transient SB               | Mild TR          |
| 6       | 13         | 2.9         | Jugular  | 5F          | Mini Thysak   | 10           | Moderate TR, dilated RA/RV |                  |
| 7       | 4          | 3.2         | Jugular  | 5F          | Sprinter legend | 5            | Transient SVT              | Severe TR, dilated RA/RV |
| 8       | 9          | 3.2         | Jugular  | 5F          | Sprinter Legend, Mini Thysak | 4.8          | Transient SB               | Severe TR, dilated RA/RV |
| 9       | 20         | 3.4         | Femoral  | 5F          | Mini Tyshak   | 5.8          | Moderate TR, dilated RA/RV |                  |
| 10      | 4          | 3.5         | Femoral  | 5F          | Sprinter Legend, Ryujin | 1.5          | Transient TAVB, RBBB       | Mild TR          |
| 11      | 28         | 3.3         | Femoral  | 5F          | Mini Tyshak   | 5.8          | Severe TR, dilated RA/RV   |                  |
| 12      | 10         | 2.9         | Femoral  | 5F          | Mini Tyshak   | 10.12        | Severe TR, dilated RA/RV   |                  |
| 13      | 28         | 3.4         | Femoral  | 5F          | Ryujin, Mini Thysak | 4.8          | Severe TR, dilated RA/RV   |                  |
| 14      | 7          | 3.3         | Femoral  | 5F          | Mini Thysak   | 4.9          | Mild TR                    |                  |
| 15      | 2          | 3.0         | Femoral  | 5F          | Ryujin, Minitrek | 2.3        | Severe TR, dilated RA/RV   |                  |

PA: Patent ductus arteriosus, TAVB: Transient atroventricular block, RBBB: Right bundle branch block, SB: Sinus bradycardia, SVT: Supraventricular arrhythmia, TR: Tricuspid regurgitation, RA: Right atrium, RV: Right ventricle

22 min, 95% CI 11-34) and fluoro time (29 ± 13 vs. 67 ± 35 min, mean difference 38 min, 95% CI 9-67.4). We did not find a significant difference in tricuspid valve (TV) crossing time.

DISCUSSION

Despite being the most common approach for BPV, using the transfemoral approach poses a significant difficulty in crossing pulmonary valve in the setting of critical PS.[14] The presence of severe TR and dilated right heart chambers in patients with critical PS make it harder to manipulate and maintain catheter position. As stated before, these features were found in the majority of our patients. In the transjugular approach, the route to enter RV from the superior vena cava is relatively straighter compared to route from the inferior vena cava (IVC) to RV using transfemoral approach. Moreover, in transfemoral approach, operator need to make one curve to cross pulmonary valve (RV to PA), whereas in transjugular approach, there are two curves that has to be made, first is from IVC to RV and the second is from RV to PA. The illustration can be seen in Figure 1. In our institution, the smallest catheter that is available to guide the wire into the PA is JR 5F. Making the loop using JR 5F in neonates is notably difficult. Therefore, the maneuver can be simplified by using transjugular approach. Even though the angle formed with transjugular approach is more likely to take the wire into right PA rather than left PA or patent ductus arteriosus (PDA), we were still able to direct the wire through the PDA to descending aorta. Anchoring the wire to descending aorta will provide better stability for balloon inflation. The easier maneuver to enter stenotic pulmonary valve using the transjugular approach leads to a significant decrease in total procedural time as shown in this study.

The total procedural time in the transjugular group is nearly half the time needed in the transfemoral group. We further divided the procedural time into TV crossing...
time, PA crossing time, and total fluoro time. Although there was no significant difference in TV crossing time, the PA crossing time was significantly shorter in the transjugular approach. This shorter amount of time then leads to shorter fluoroscopy time and radiation exposure. Mean fluoro time in transjugular group was less than half time in the transfemoral group. Several studies have mentioned that the risk of cancer from radiation exposure is inversely proportional with age, meaning that radiation exposure will have greater impact to newborn than older children or adult.\textsuperscript{[11]} The feasibility of the transjugular approach for BPV in children was demonstrated in several publications. Senzaki et al.\textsuperscript{[7]} successfully used this approach in 14 children (4 months to 13 years old) undergoing BPV. He mentioned that no complication occurred from either the puncture or balloon dilatation procedure itself. Furthermore, crossing the pulmonary valve was much easier from IJV than from femoral vein, especially with the use of dilatation balloon catheter which is more difficult to manipulate than the ordinary catheter. Chaara et al.\textsuperscript{[4]} and Joseph et al.\textsuperscript{[3]} also used this approach after failed attempts using the transfemoral approach. Our study, however, is the first study that directly compares between the transjugular and transfemoral approach in neonates.

Another point to be mentioned is that in our study, we did not perform transjugular approach under ultrasound guidance. The use of ultrasonography may facilitate cannulation and contribute to shorter procedural time.\textsuperscript{[12]} Hence, in some circumstances, ultrasound-guided cannulation may be preferred. Several complications related to IJV cannulation had been reported in some literatures, which include pneumothorax, hydrothorax, injury to the vagus, phrenic and other nerves, sagittal sinus thrombosis, thoracic duct puncture, laryngeal edema, and vertebral artery pseudoaneurysm.\textsuperscript{[5,7]} These complications, although very rare, are very serious and commonly happens while performed by inexperienced operators. However, in this study, no complication regarding the vascular access occurred in both groups. The sheath size also did not appear to be a problem, since we were able to use the same 5F size in both groups. Higher postballoon dilatation related complications in transjugular approach simply reflecting the hemodynamic alteration in RV and PA, which author believes was not related to the vascular access.

CONCLUSION

Shorter procedural time and low rate of complication make the transjugular approach a better choice for BPV procedure in critical PS. Most importantly, it can minimize radiation exposure to our patients.

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Conflicts of interest

There are no conflicts of interest.

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