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Transcatheter closure through single venous approach for young children with patent ductus arteriosus

A retrospective study of 686 cases

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Abstract

The objective is to explore the feasibility and safety of transcatheter closure of patent ductus arteriosus (PDA) through single venous approach in Chinese young children.

A total of 1088 patients aged between 9 months old to 3 years old who underwent transcatheter closure of PDA from May 2004 to May 2015 were retrospectively reviewed. All the procedures were under ultrasound monitoring. The shape and size of PDA as well as immediate therapeutic results were recorded by angiography and ultrasonography. The size of occluder was individually selected according to the smallest diameter of the PDAs. Echocardiography was respectively performed 3 days, 1month, 6 months, and 12 months after the procedure to evaluate the outcomes.

Among the total 1088 children, transcatheter closure of PDA was accomplished through single venous approach that was performed in 686 cases. The average weight and age of the children were 10.9 ± 3.6 kg (5.0–14.3 kg) and 1.8 ± 1.6 years (9 months–3 years), respectively. The fluoroscopic time was about 5.1 to 11.6 minutes. Successful device placement with the initially selected occluder was achieved in 662 cases. In other 14 cases, the procedure was eventually completed after being replaced with a larger occluder; while in the other 10 cases, smaller occluders were applied to replace the initial ones. Technically, all the procedures were successfully performed. All the patients were followed up for 15.6 ± 8.2 years. No serious complications and death were observed during the follow-up.

Transcatheter closure of PDA with occluder by single venous approach is an effective and reliable method in vast majority of young children.

Abbreviations: AV = arteriovenous, PDA = patent ductus arteriosus, WMA = World Medical Association.

Keywords: patent ductus arteriosus, single venous approach, transcatheter closure, young children

1. Introduction

Patent ductus arteriosus (PDA) is a heart problem that occurs soon after birth in some infants and accounts for 10% to 16% of all congenital defects.[1] PDA should be given more attention in children due to its related symptoms including heart failure, frequent respiratory infection and failure to thrive, etc. Transcatheter closure of PDA has been routinely recommended to eliminate the adverse outcomes.[2–5] The standard method for transcatheter closure of PDA is the transvenous procedure: through the femoral vein under guidance of aortic catheter accessed from femoral artery route.[6] Apart from the complications resulted from femoral artery caused complications, other potential issues including bleeding, longer catheterization and fluoroscopic time, and probably prolonged hospital stay should also be taken into consideration, especially in children with lower body weight.[7] In this study, we presented a comprehensive review of transcatheter PDA device closure in 1088 young children over a period of 11 years.

2. Methods

2.1. Patients

A total of 1088 patients (age: 9 months to 3 years) who underwent transcatheter closure of PDA from May 2004 to May 2015 were retrospectively reviewed. Their medical records, echocardiographic findings, hemo-dynamic data, and follow-up results were synthetically analyzed. Informed consents were obtained from the guardians of patients when retrieving their information. Medical diagnosis of PDA was based on the examination by echocardiography in all patients. Patients with continuous murmur checked by physical examination, PDA diameter larger than 1 mm on echocardiography, symptomatic

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Written informed consent was obtained from the patient from their parents or legal guardians of the patients for publication of this report and any accompanying images. A copy of the written consent is available for review by the Editor of this journal.

This study was performed according to the World Medical Association (WMA) Declaration of Helsinki under the Policy of "Ethical Principles for Medical Research Involving Human Subjects." All patients provided informed consent and parental consent was obtained for participants under 16, and the protocols were under the approval by the Ethics Commission of the Institutional Review Board of the First Hospital of Hebei Medical University.

The authors have no conflicts of interest to disclose.

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ones on account of left to right shunt, and those with signs of left ventricular-atrial volume overloading were included.

Transcatheter closures of PDA were performed in the catheterization laboratory following fluoroscopy guidance. An elaborate echocardiographic evaluation of duct morphology was carried out in all patients undergoing PDA closure as a part of the institutional protocol. Just after the echocardiogram, the device closure was well prepared. Transcatheter closure through single venous approach was brought into operation in all patients except those with the following situations when arterial access was considered necessary: patients with inadequate echocardiographic definition; patients with large ducts with severe pulmonary artery hypertension that required a diagnostic study to assess pulmonary vascular resistance for reversibility prior to attempted device closure; patients with additional lesions requiring intervention through artery approach. Among the total 1088 children, transcatheter closure of PDA was accomplished through single venous approach in 686 cases. Cases who received transcatheter closure of PDA through both veins and arteries were excluded.

2.2. Catheter intervention procedure

Every patient received general anesthesia before operation. Five French sheaths were placed in the femoral veins before administration of heparin (100 U/kg). Another 5 French right cardiac catheters were implanted through the inferior caval vein, right atrium, right ventricle, and main pulmonary artery. During the procedure, the blood pressure was monitored. Then the catheter was used to pass through the duct from the main pulmonary artery with the help of the straight end of a 0.025 or 0.035 inch guidewire. Then the catheter was replaced with the guidewire (0.035 cm × 260 cm) that the loop of the pigtail catheter was left in the aorta (Fig. 1). Aortography was conducted, and the anatomical measurement of PDA diameter was estimated accordingly (Fig. 2). After that, the occluder in

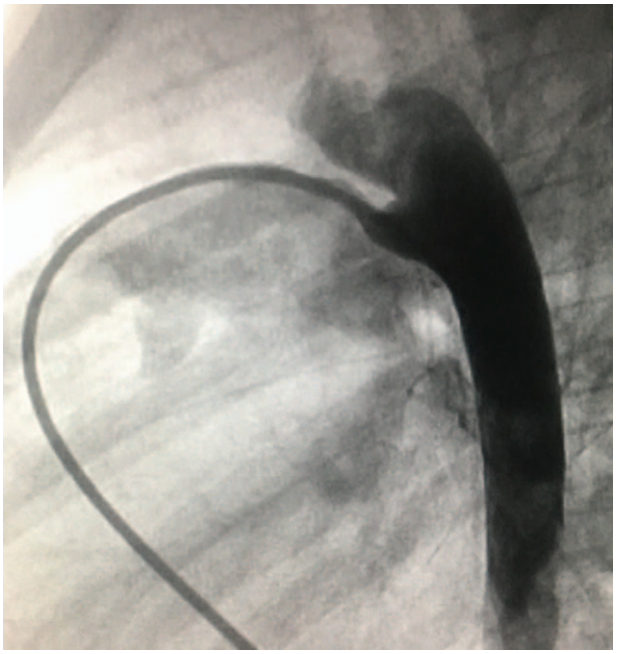

Figure 1. Aortography performed in left lateral position with the pigtail catheter placed inside the duct.

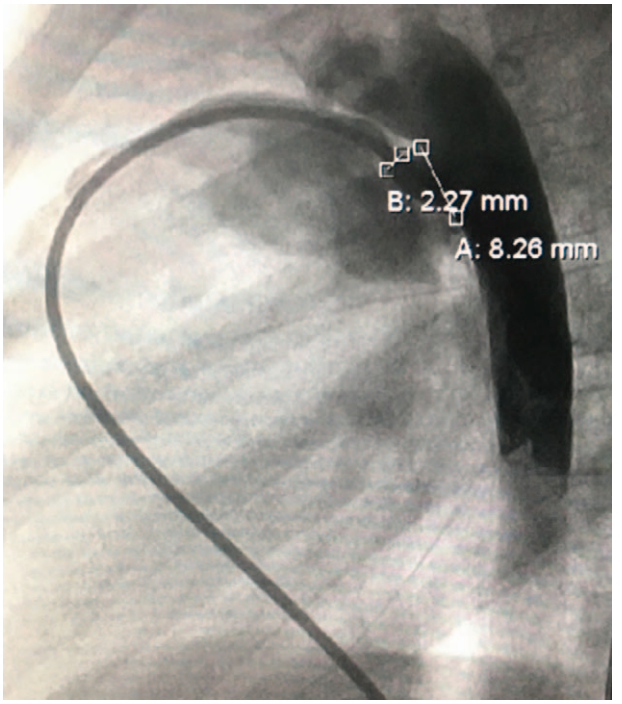

Figure 2. The anatomy and the measurement of PDA diameter. PDA = patent ductus arteriosus.

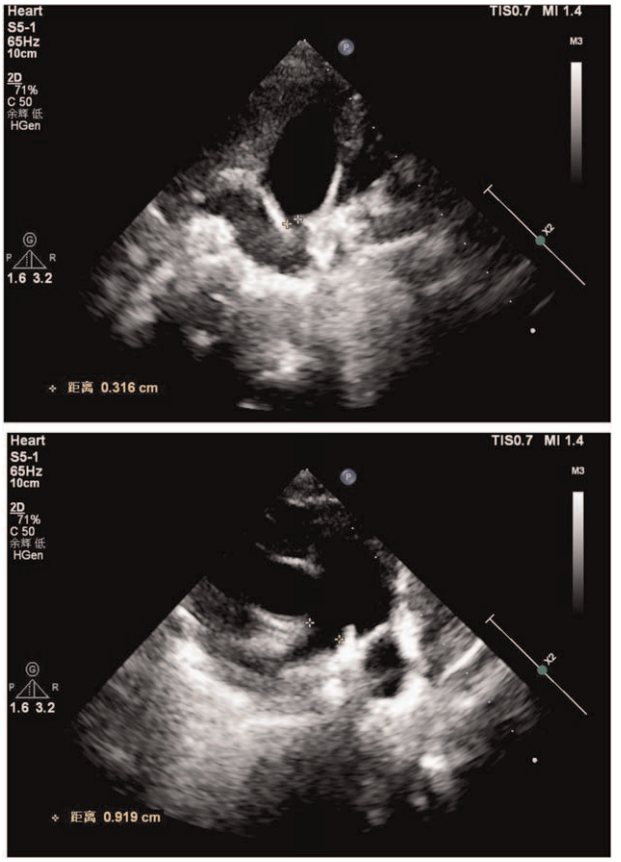

Figure 3. A detailed echocardiographic evaluation of duct morphology was performed in patients underwent PDA closure. PDA = patent ductus arteriosus.

suitable size was selected according to the results of aortography and echocardiography (Fig. 3). The diameter was about 1 to 2 mm larger than the diameter of the narrowest point of the duct. The catheter was substituted by an appropriate long sheath over an exchange length extra-stiff guidewire. The duct was profiled in lateral view. Furthermore, the occluder was implanted following the standard method but the only difference was that the control aortography was not performed (Fig. 4). The position of the occluder was determined by the aortography and echocardiography performed in the cardiac catheterization laboratory before releasing the device. The device was assessed on a 2-dimensional echocardiography in high parasternal view and suprasternal view. The devices used for ductal closure were obtained from Lifetech Duct Occluders (Shenzhen Lifetech Scientific Inc. Shenzhen, China).

2.3. Follow-up

Twenty-four hours after the procedure, complications like arrhythmia, embolization, left pulmonary artery stenosis, and residual shunt were monitored by physical examination, electrocardiography, and echocardiography. Transthoracic echocardiography was used to evaluate prognosis at different time points (3 days, 1 month, 3 months, 6 months, and 1 year) after the operation.

3. Results

Generally, a total of 1088 patients received transcatheter closure of PDA. Among them, the procedure was accomplished using single venous approach in 686 patients (male: 228, female: 458). The average body weight and age were 10.9 ± 3.6 kg (5.0–14.3 kg) and 1.8 ± 1.6 years (9 months–3 years), respectively. In addition, 16 patients were excluded from the study in that arteriovenous (AV) loop was formed with noodle guidewire since their PDAs could not be reached through the venous route.

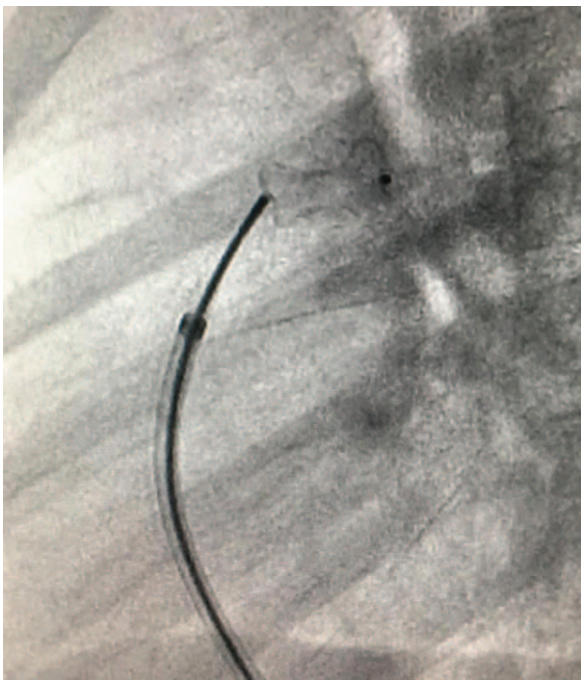

Figure 4. The occluder was implanted following the standard method.

The procedure time was 21.6 ± 6.3 minutes (15.0–27.8 minutes) and fluoroscopy time was 8.4 ± 3.2 minutes (5.1–11.6 minutes). The sizes of occluders ranged from 4 to 12 mm with the mean value of 6.9 ± 3.6 mm. In 662 cases, the occluder was appropriately chosen. In 14 cases, the procedure was eventually completed after replacement of a larger occluder while in 10 cases the occluders were replaced with smaller ones. The technical success rate was 100%. During the follow-ups, no any complications like arrhythmia, vascular access, hemolysis, and massive blood loss occurred. The residual flow in 23 patients disappeared within 24 hours after the procedure. Echocardiographic examination demonstrated that complete closure of PDA was found in all patients during the follow-up (average time: 15.6 $\pm$ 8.2 months). No stenosis in the pulmonary arteries or aorta was found and no death appeared during the study.

4. Discussion

Transcatheter closure of PDA is a reliable and effective procedure in which various devices have been used.[8–14] However, a great number of complications such as hemolysis, device embolization, infection, and significant narrowing of the left pulmonary artery or the descending aorta have been reported in previous publications.[8,15] Vascular access has been identified as one of the most significant complications of interventional PDA occlusion,[16] especially in those children with lower body weight.[7,17,18] Previous research has revealed that an additional arterial approach was used for pressure monitoring and contrast injection was required when an antegrade procedure was applied in the transcatheter closure of PDA.[19] As arterial access allows initial aortography to be performed without crossing the duct, it can minimize the risk of ductal spasm and consequent underestimation of the size of the duct. In addition, it permits subsequent aortography to locate a good position of the device prior to release and exclude iatrogenic coarctation.

Accumulating experiences have indicated that ductal spasm might occur whether the duct is crossed or not.[20,21] Such reaction of the duct walls is prone to happen in younger patients whose fibrosis or calcification has not completely developed. It is important to be aware of the possibility of such situation, especially for the differences between the diameter of the duct before and during the procedure. In this study, we found that the operations of 14 cases could not proceed until a larger occluder was introduced to replace the initial one.

Avoiding the arterial access by single venous approach could eliminate nearly all possible complications associated with arterial puncture: occlusion, embolism, dissection, pseudoaneurysm formation, and bleeding, etc. However, what makes it tough in this method is the lack of precise angiographic imaging immediately before the deployment of the device. Based on our experience, good echocardiographic image is sufficient for the safety of the procedure. The experienced echocardiographer is able to determine the location of the occluder accurately. During the echo imaging we are able to estimate the blood flow both in the aorta and pulmonary arteries to ensure that none of the vessels (especially the left pulmonary artery) are narrowed.[22] An additional advantage of our method is the reduction of the volume of contrast medium to avoid adverse effects when utilizing contrast agent in young children. This method is also considerably efficient to shorten fluoroscopy time and hospital stay.[23]

The guidewire cannot go through the arterial duct from the pulmonary artery. In such a situation it is impossible to perform PDA closure only by the venous approach. In this study,

16 children were excluded in which arteriovenous loop was formed with noodle guidewire since their PDA could not be reached through the venous route.

This study demonstrated the feasibility of closure of the PDA by single venous approach. In this consecutive series of 1088 young children, we were able to close PDAs in 686 patients with venous access alone. The critical steps in this study are careful selection, confirmation of the location of the occluder, and assessment of residual flows by echocardiographic imaging. The method that we have described can be used as an alternative to the standard method, especially in complicated situations in which even the experienced echocardiographers and interventionalists cannot fully handle.

5. Conclusion

The transcatheter closure of PDA with occluder by single venous approach is an effective and reliable method in vast majority of young children including infants.

Author contributions

Conceptualization: Jun Liu, Zhen Wang.
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Visualization: Zhen Wang.
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