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Application of single venous approach under echocardiography without angiography in closure of Patent Ductus Arteriosus

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Abstract

Background The conventional arteriovenous approach closure of patent ductus arteriosus (PDA) may be associated with more complications, especially in young infants. The objective is to explore the feasibility and clinical efficacy of interventional closure of PDA through a single venous approach under echocardiography without angiography.

Methods 112 patients (32 males and 80 females) with PDA closed by different methods in Suining Central Hospital were enrolled, including 60 cases (Group 1) with a single venous approach under echocardiography without angiography and 52 cases (Group 2) with the conventional arteriovenous approach. There were no significant differences in age and gender composition between the two groups. The success rate of operation, complete closure rate of 24 h, procedure time, X-ray fluoroscopic time, radiation dose, intraoperative contrast volume, preoperative and postoperative creatinine, preoperative and postoperative uric acid nitrogen, bed rest time, total hospital stay, and incidence of vascular complications were compared between the two groups.

Results There were no significant differences in the success rate of operation (100% vs. 100%) and the complete closure rate of 24 h (100% vs. 100%) between the two groups ($P > 0.05$). In the single venous approach group, the procedure time was (50.05 ± 4.78 min vs. 57.69 ± 6.44 min), the X-ray fluoroscopy time was (7.30 ± 0.78 min vs. 10.23 ± 1.58 min), and the radiation dose was (79.57 ± 15.18mGy vs. 219.22 ± 34.60mGy), contrast volume (0mL vs. 62.22 ± 22.69 ml), bed rest time (4.03 ± 0.99 h vs. 12.25 ± 1.73 h), total hospital stay (3.30 ± 0.52 days vs. 3.39 ± 0.49 days) and the incidence of vascular complications (0% vs. 13.9%) were significantly lower than those in the traditional angiography group ($P < 0.05$). There were no significant changes in creatinine (51.86 ± 12.75 umol/L vs. 53.09 ± 10.27 umol/L) and urea nitrogen (4.84.81 ± 1.21 mmol vs. 4.98 ± 0.93 mmol/L) before and after operation in single venous group ($P > 0.05$). Compared with preoperative creatinine level (68.23 ± 8.66umol vs. 59.23 ± 22.12umol) and urea nitrogen level (5.98 ± 1.13 mmol/L vs. 5.16 ± 1.49 mmol/L) in the traditional angiography group after operation (24 h), they were significantly increased ($P < 0.05$).

Conclusions Compared with the conventional arteriovenous approach, the single venous approach has the outstanding advantage of reducing vascular complications, contrast volume, radiation dose, and procedure time. Compared with the conventional arteriovenous approach, on the basis of obtaining the same efficacy, the PDA occlusion of the single venous approach under echocardiography without angiography has the outstanding

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advantages of simplified operation, less X-ray radiation, no contrast agent injury, short bed rest time, and fewer vascular complications. It is a green and safe surgical method worth promoting for PDA patients with suitable anatomical conditions.

Keywords Single venous approach, Patent ductus arteriosus, Conventional arteriovenous approach, Echocardiography

Background

As an isolated lesion, patent ductus arteriosus (PDA) is one of the most common congenital diseases, accounting for 5–10% of all congenital heart diseases [1]. Since the first percutaneous transcatheter closure of PDA was reported by Portsmann et al. in 1967 [2]. Transcatheter PDA closure has become the leading choice of treatment for patients due to its advantages of fewer complications and a shorter recovery period [3, 4]. The conventional arteriovenous approach for transcatheter closure of PDA requires puncture of both the femoral artery and vein: arterial access for delineating the size and anatomy of PDA, while device deployment is performed via the venous route [5]. However, the conventional arteriovenous approach closure of this procedure may be associated with vascular complications, the rates of which have ranged from 9.3 to 16% in various studies [6, 7] .These vascular complications are related to the size of the patient's body and the arterial sheath used, especially in smaller patients. Apart from vascular complications, the use of iodinated contrast media may result in contrast-induced acute kidney injury [8]. Moreover, longer fluoroscopic time has raised concerns regarding radiation exposure [9]. The aim of this study was to report the experience of PDA device closure using a single venous approach under echocardiography without angiography in the center of the single and to compare outcomes with the conventional arteriovenous approach.

Methods

Study design and patient selection

A total of 112 patients(32 males and 80 females)with PDA who received interventional treatment in Suining Central Hospital from January 2017 to May 2022 were included. According to different interventional treatment methods, the patients were divided into two groups: Group 1 included 60 patients (15 males, 45 females, age 18.92±18.21 years, BMI 18.53±4.05 kg/m2) who underwent a single venous approach under echocardiography without angiography. Group 2 included 62 patients (17 males, 35 females, age 17.79±16.41 years, BMI 17.92±3.13 kg/m2) who underwent the conventional arteriovenous approach. There were no significant differences in age, gender, and BMI between the two groups ($P>0.05$) (Table 1). All patients were diagnosed with PDA by clinical physical examination, electrocardiogram, chest X-ray, and transthoracic echocardiography (TTE).

Inclusion criteria: (1) Weight above 4 kg; (2) audible cardiac murmur, volume overload, and symptomatic patients attributed to PDA; (3) funnel-shaped patent ductus arteriosus; (4) resistance significant pulmonary hypertension. exclusion criteria: (1) combined with other congenital cardiovascular malformation requiring surgical repair; (2) large PDA; (3) right-to-left shunt across the PDA.

Ethics

The study was approved by the ethics committee of Suining Central Hospital, and written informed consent was obtained from the patients' parents. All subjects gave written informed consent in accordance with the Declaration of Helsinki.

Procedure

Single venous approach under echocardiography without angiography

The surgery was completed in the interventional catheterization room. The shape and position of the PDA were evaluated under echocardiography before the procedure. The narrowest width of the arterial duct in multiple views, such as the standard parasternal short axis view, the supra-sternal long axis view, and the high parasternal short axis view, was measured. At the same time, the blood flow velocity of the proximal descending aorta and the origin of the left pulmonary artery were recorded as preoperative reference values. Local lidocaine was used for patients over 12 years old, and general anesthesia was used for children under 12 years old or unable to cooperate with preoperative fasting for 6 h. The six French short sheaths were inserted into the right femoral vessels before 50 U/kg heparin was administered to the patients after cannulation. A 5 French MPA catheter was implanted through the right femoral vein→ right atrium→ right ventricle→ pulmonary artery→ ductus arteriosus→ descending aorta with the assistance of the under guidewire guidance. Then, the 0.035-inch, 260-cm guidewire exchanged MPA to establish the track. Then the MPA catheter was replaced with the guidewire (0.035 cm x 260 cm), and the head end of the guidewire was left in the descending aorta without angiography. The occlude was selected as approximately 3–6 mm larger than the narrowest width of the arterial duct measured under TTE. Before releasing the device, the appropriate and stable position was accepted when the retention skirt was

Table 1 Demographics of the studied groups

	Group 1($n=60$)	Group 2($n=52$)	χ^2/t-value	*P*-value
Gender, *n*(%)			0.808	0.369
Male	15(25)	17(32.7)		
Female	45(75)	35(67.3)		
Age(years)	18.92 ± 18.21	17.79 ± 16.41	0.342	0.733
BMI(kg/m^2)	18.53 ± 4.05	17.92 ± 3.13	0.879	0.381

seen opposing the ampulla in the descending aorta and embedding it into the ductal ampulla under fluoroscopy guidance. The rest of the device was then displayed in the pulmonary artery end. Before the device was unscrewed, the shape and position of the occluder were again evaluated by TTE through multiple views. If the results of the occluder were not satisfactory, replace the appropriate occluder and repeat the above process until satisfactory results were achieved.

Conventional arteriovenous approach

According to the conventional closure procedure, the anesthesia methods were the same as the single venous group. The right femoral artery and the right femoral artery were punctured, respectively. The 6 French MPA catheter implanted through the right femoral vein was routinely used for right heart catheterization. In the origin of the descending aorta, the aortography view in the left lateral view 90° was performed using a 5 French pigtail catheter to record the position, shape, and diameter of the ductus arteriosus.The track establishment procedure was the same as the heparin dose used in the single venous group. The track establishment procedure and heparin dosage in the conventional arteriovenous group were the same as those in the single venous group. The device was deployed from the descending aorta end. Before releasing the device, aortography was repeated to ensure the accurate position and shape of the occluder.

Device detail

The most frequently used device in our institution was the mushroom occluder, produced by Shape Memory Alloy (Shanghai, China).

Follow-Up

Twenty-four hours after the procedure, the success rate of operation, complete closure rate, operation time, X-ray fluoroscopic time, radiation dose, intraoperative contrast volume, preoperative and postoperative creatinine, preoperative and postoperative uric acid nitrogen, bed rest time, total hospital stay, and incidence of vascular complications were compared between the two groups. All patients underwent TTE, X-ray, and electrocardiography to evaluate prognosis at different time points (3 days, 1 month, 3 months, 6 months) after the operation.

Table 2 Procedure results

	Group 1($n=60$)	Group 2($n=52$)	χ^2/t-value	*P*-value
Success(%)	60(100%)	52(100%)	-	1.000
Closure rate of 24 h(%)	60(100%)	52(100%)	-	1.000
Procedure time(min)	50.13 ± 4.80	57.37 ± 5.82	−7.208	< 0.001
Fluoroscopy time(min)	7.27 ± 0.75	10.11 ± 1.49	−13.029	< 0.001
Radiation dose(mGy)	78.98 ± 14.62	220.21 ± 33.35	−29.692	< 0.001
Contrast volume(ml)	0	62.69 ± 23.44	−20.731	< 0.001
Bed rest time(hour)	4.00 ± 0.92	12.38 ± 1.61	−34.375	< 0.001
Total hospital stay(day)	3.33 ± 0.57	3.37 ± 0.49	−0.317	0.752
Vascular complications(%)	0(0)	6(11.5)	-	0.009

Statistical analysis

SPSS 26.0 software (IBM Corp., Armonk, NY, USA) was used for data analysis. If the measurement data were normal distribution, they were represented by X ± s. The comparison between the two groups was performed by two independent sample t-tests. Enumeration data were expressed as frequency (percentage), and the chi-square test was used for comparison between groups. $P<0.05$ was considered statistically significant.

Result

Successful closure of patent ductus arteriosus was achieved in all patients. Cardiac murmurs disappeared, left ventricular shrinkage, no death, no arrhythmia, and residual shunt in all patients. There were no significant differences in the success rate of operation (100% vs. 100%) and the complete closure rate of 24 h (100% vs. 100%) between the two groups ($P>0.05$) (Table 2). The operation time, X-ray fluoroscopy time, radiation dose, intraoperative contrast agent dosage, bed rest time, and total hospital stay in Group 1 were lower than those in Group 2 ($P<0.05$). There were no vascular complications in Group 1, while there were fewer vascular complications in Group 2, including hematoma (4 cases) and femoral arteriovenous fistula (2 cases). The incidence of vascular complications in group 1 was significantly lower than that in group 2 (0% vs. 11.5%, $P<0.05$) (Table 2). There were no significant changes in creatinine (52.93 ± 13.65 umol/L vs. 53.75 ± 9.51 umol/L) and urea nitrogen (4.75 ± 1.10 mmol/L vs. 4.98 ± 0.88 mmol/L) before and after operation (24 h after operation) in group 1 ($P>0.05$). Compared with preoperative creatinine levels (58.33 ± 20.8umol vs. 67.39 ± 7.68umol) and urea nitrogen levels (5.11 ± 1.45mmol/L vs. 5.99 ± 1.10mmol/L) were increased in different degrees ($P<0.05$) (Table 3).

Table 3 Creatinine and uric acid nitrogen

	n	creatinine		uric acid nitrogen	
		preoperative	postoperative	preoperative	postoperative
Group 1	60	52.93 ± 13.65	53.75 ± 9.51	4.75 ± 1.10	4.98 ± 0.88
Group 2	52	58.33 ± 20.84	67.39 ± 7.68[a]	5.11 ± 1.45	5.99 ± 1.10[a]
t-value		−1.643	−8.261	−1.492	−5.366
P-value		0.103	<0.001	0.139	< 0.001

Note: Compared with preoperative, a $P<0.05$。

Discussion

As catheterization techniques develop and spread, transcatheter occlusion has become the leading choice of treatment for PDA in the last decade [3, 4]. Conventional transcatheter device closure of PDA involves placement of an angiographic catheter via the femoral artery access. When the literature was reviewed, most of the studies reported a high incidence of success rate of 94%, and the rate of major average events was 1.5% [10, 11]. With the development of new devices, the success rate is gradually increasing. Unfortunately, it carries serious adverse effects, including vascular complications, radiation, and acute renal failure. Hematoma, artery occlusion, arteriovenous fistula, loss of pulse, and pseudoneurosis are often associated with femoral artery access, particularly in infants. Tadphale et al. [12] demonstrated access to femoral artery < 3 mm and OD/AD ratio > 50% were associated with increased incidence of loss of pulse following cardiac catheterization in infants. Furthermore, the conventional device closure of PDA is not suitable for patients who have abnormal renal function. Scholars have been trying to use different approaches to reduce the negative impact on patients. In an effort to overcome the above vascular complications, Zhou and Liu et al. [13, 14] started using venous access with angiography in the closure of Patent Ductus Arteriosus. The disadvantage was that the crossing of the PDA for initial sizing may induce ductal spasm and consequent downsizing of the device [15]. To avoid radiation and contrast agents, the single femoral artery approach under TTE guidance was applied to the transcatheter device (ADO II) closure of PDA in recent literature [15, 16]. For arterial access, ADO II occluder was not only a problem of vascular complications but also unsuitable for PDA patients with a diameter larger than 5.5 mm [17, 18]. Besides, single TTE guidance also has inherent drawbacks compared with fluoroscopic guidance, such as a smaller image interface and limited operating view [19].To our knowledge, few studies were reported for transcatheter closure of patent ductus arteriosus from a single venous approach under echocardiography without angiography. We are the first to systematically report the single venous approach and to provide a detailed analysis. In this study, 60 cases in Group 1 were reported by a single venous approach under echocardiography without angiography, with satisfying feasibility and safety. The.

single venous approach under echocardiography without angiography, with satisfying feasibility and safety. The single venous approach under echocardiography without angiography successfully avoided vascular complications and reduced the damage caused by contrast agents and X-rays. It is especially suitable for patients with contrast allergies and infants. The single venous approach in Group 1 greatly reduced operation time and contrast volume compared with the control group in Group 2. The reduction in operative time and contrast volume usage reflected the reduction in radiation dose, which was beneficial to both patients and doctors [20]. Of course, the reliability of TTE measurements is critical for proper device size. In Paudel's study [21], TTE measurements are comparable to angiographic measurements, thereby assisting in appropriate device size selection. In Group 1, the shape, position, and size of the PDA were evaluated by preoperative echocardiography instead of descending aortography, and the position of the occluder was determined by the aortography and echocardiography performed before releasing the device, making the entire procedure easier and less invasive.

There are several limitations to this study. (1) Descending aortography was not performed during the entire procedure, and there was a blind area in the reference point before the occluder was released. (2) If the operators were inexperienced, it would easily lead to inappropriate selection of occluder size, unsatisfactory release position, and the increased probability of repeated attempts to release, thus increasing the risk of PDA or pulmonary artery intima injury. It requires the perfect cooperation of the radiologists and the TTE operators and is not suitable for beginners to carry out. (3) A single venous approach under echocardiography without angiography is suitable for typical funnel-type PDA. For long tube-type PDA, especially those with a small pulmonary artery end, it is difficult to establish the track through the pulmonary artery end.

Conclusion

The single venous approach under echocardiography without angiography is a simple, safe, and reliable operation with fewer vascular complications of new technology compared to conventional arteriovenous approaches.

Its exact clinical value needs more large-scale clinical practice to verify.

Author contributions
Yiwei He who is the Corresponding author was the intervetionist who performed all of the operations. Pan Xiong was responsible for writing the paper, Chen Quan was responsible for data collection, and He Yiwei was responsible for revising the paper.All authors have intellectually supported the study. All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was approved by the ethics committee of Suining Central Hospital. All participants were informed of the details of the study and singed a consent form.All subjects gave written informed consent in accordance with the Declaration of Helsinki.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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