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Article

Comparison of Long-Term Clinical Outcomes and Costs of Two Interventional Closure Routes in the Treatment of Patent Ductus Arteriosus in Children

Qiuqing Ke[1], Guoxing Weng[2], Qi Xie[2], Juntao Li[2], Jiayin Bao[2], Fuzhen Zheng[2], Jie Huang[2], Licheng Yan[2], Haiyu Chen[2,*]

[1]Department of Internal Medicine, Shengli Clinical Medical College of Fujian Medical University, Fujian Provincial Hospital, Affiliated Provincial Hospital of Fuzhou University, 350001 Fuzhou, Fujian, China
[2]Department of Cardiovascular Surgery, Shengli Clinical Medical College of Fujian Medical University, Fujian Provincial Hospital, Affiliated Provincial Hospital of Fuzhou University, 350001 Fuzhou, Fujian, China
*Correspondence: 9315217@qq.com (Haiyu Chen)

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Abstract

This study aimed to compare the long-term clinical outcomes and costs between the conventional arteriovenous (CA) and simple venous (SV) approaches for treating patent ductus arteriosus (PDA) in children. Demographics, preoperative clinical conditions, technical indices, cost, acute complications, follow-up outcomes, and pre- and postoperative left ventricular end-diastolic diameter (LVEDD) and pulmonary artery (PA) diameter were compared between the CA (n = 96) and SV (n = 82) groups using appropriate statistical analyses. No significant differences were observed in demographics and preoperative clinical conditions between the CA and SV groups. The initial successful closure rates were comparable between groups; however, the SV group had significantly shorter operating times ($p < 0.001$) and lengths of stay ($p < 0.001$). Costs were significantly higher in the CA group ($p < 0.001$). Acute complications were less frequent in the SV group ($p < 0.001$), with lower rates of femoral artery and vein injuries ($p < 0.001$) and total complications ($p < 0.001$). Follow-up outcomes, including death, late recanalization, and left ventricular overload, did not differ significantly between groups. Postoperative LVEDD and PA diameter showed significant reductions in both groups, with no statistically significant difference between them. SV PDA closure is a safe and effective procedure, with lower complication rates and costs. Long-term follow-up outcomes and postoperative changes in LVEDD and PA diameter were similar between the two approaches.

Keywords

clinical efficacy; costs; interventional closure; patent ductus arteriosus

Introduction

Patent ductus arteriosus (PDA) is a common congenital heart defect characterized by the persistence of a fetal blood vessel connecting the pulmonary artery and the descending aorta [1–3]. PDA accounts for a significant portion of cardiovascular abnormalities in pediatric patients. Traditional treatment options for PDA have included surgical ligation and medical management. However, advancements in interventional cardiology have led to transcatheter closure becoming a widely used alternative, offering less invasive options with potentially shorter recovery times [4–6].

Two primary approaches have emerged for transcatheter closure of PDA: the conventional arteriovenous (CA) approach and the single-view (SV) approach. While both techniques aim to achieve successful PDA closure, the methods differ in their procedural techniques and potential outcomes [5–8]. While previous studies [9–11] have explored the short-term efficacy and safety of these closure routes, a gap remains in the understanding of their long-term clinical outcomes and economic implications. Therefore, this study aimed to compare the long-term clinical outcomes and costs associated with the CA and SV approaches for treating PDA in children. Moreover, elucidating the differences in outcomes and costs between these two techniques can promote informed clinical decision-making and optimize patient care in the management of pediatric PDA.

Materials and Methods

Patient Selection Criteria

This study analyzed data from pediatric patients diagnosed with PDA who underwent interventional closure procedures between January 2006 and January 2019 at Fujian Provincial Hospital. Written informed consent was ob-

tained from the parents, legal guardians, or next of kin of each participant before their inclusion in the study. The protocol for this study was reviewed and approved by the Fujian Provincial Hospital Ethics Committee. This study was conducted in accordance with the principles outlined in the Declaration of Helsinki [12,13]. All procedures were performed with respect for the rights and confidentiality of the patients. The data collected during the study were anonymized to ensure patient privacy. Patients were classified as receiving CA access or SV access based on their clinical status or their surgeon's preference after considering: (1) the PDA characteristics (isolated 3–10 mm PDAs preferred for SV), (2) vessel condition (CA contraindicated in severe peripheral artery disease), and (3) patient factors (patients with venous thrombosis or requiring anticoagulation). Of the 178 patients, 96 underwent CA, and 82 accepted SV with transcatheter Amplatzer occlusion for PDA closure. The inclusion criteria specified patients who weighed at least 4 kg and had a PDA diameter smaller than 14 mm. All PDA were closed using the Amplatzer Duct Occluder I (8474108, Abbott Medical, Plymouth, Minnesota, USA).

The exclusion criteria ruled out PDA patients with severe pulmonary arterial hypertension with right-to-left shunting, pulmonary vascular resistance >14 woods; concurrent cardiac anomalies requiring surgical correction; patients dependent on PDA for survival; infective endocarditis, cardiac valve lesions, and intracardiac vegetations; patients with other conditions unsuitable for surgical or interventional treatment [12,13].

Pre- and Postoperative Protocols

For each enrolled patient, a physical examination, chest roentgenography, electrocardiography, and echocardiography were performed pre- and postoperatively. A chest roentgenography was performed to measure the cardiothoracic ratio and to assess the arrhythmia electrocardiographically. An echocardiography was systematically performed to evaluate cardiac-related factors, such as left ventricular end-diastolic diameter (LVEDD), pulmonary artery diameter, left ventricular ejection fraction (LVEF), and peak systolic pulmonary artery pressure. Echocardiography was also used to determine the size and length of the ductus, to test for residual shunting postoperatively, and to detect the position of the occluders.

The clinical outcome measures included successful PDA closure, operating time, length of stay (defined as the period from procedure completion to discharge), incomplete closure requiring subsequent occlusion procedures, and acute complications. The cost analysis was based on the average hospital cost between the two groups, including the costs for operations, materials, medicines, bed charges, nursing care, and other related expenses.

Follow-Up Methods and Endpoints

All patients who successfully underwent CA and SV for PDA closure underwent a follow-up using one of three methods: outpatient visits, letters, or telephone calls, which included chest roentgenography, electrocardiography, and echocardiography.

PDA Closure Techniques

CA: Transcatheter PDA closure via femoral arteriovenous catheter under fluoroscopy: (1) Routine surgical preparation and anesthesia methods were employed: the right femoral artery and vein were punctured, and a left and right heart catheterization was conducted if necessary. (2) A pigtail catheter was inserted into the aortic arch descending segment for angiography to clarify the morphology, position, and size of PDA. (3) A 0.035″ J-tip exchange wire (200 or 260 cm) was introduced through the descending aorta into the pulmonary artery, then inserted through the femoral vein into the pulmonary artery, and the J-tip wire was removed from the body to establish an arteriovenous wire pathway. (4) The delivery sheath was advanced along the exchange wire to the level near the diaphragm, and the inner core and wire were removed from the delivery sheath. (5) Typically, a mushroom umbrella occluder is chosen, with a diameter generally 3–6 mm larger than the narrowest diameter of the PDA. In infants and young children, the PDA tissue elasticity is high, and the diameter of the occluder should be twice the diameter of the PDA. The occluder is advanced through the delivery sheath to the distal end of the sheath. Under fluoroscopy, the umbrella disc is first opened on the aortic side. Then, the delivery sheath and occluder are withdrawn into the PDA. The delivery cable is secured, and the sheath is withdrawn to the pulmonary artery side of the PDA, trapping the waist of the occluder inside the PDA. (6) Angiography of the aortic arch descending segment is repeated after 10 minutes. If there is no residual or minimal shunt, no significant murmur is detected on auscultation, and no significant pressure difference exists between the left pulmonary artery and the main pulmonary artery, as well as between the ascending and descending aorta, and the occluder morphology and position are appropriate, the occluder can be fully released. (7) The right heart catheterization process is repeated. After sheath withdrawal, compress the puncture site to stop bleeding and apply a pressure bandage dressing.

SV: Transcatheter PDA closure via femoral vein catheter under fluoroscopy: (1) Routine surgical preparation and anesthesia methods are employed, and the right femoral vein is punctured. (2) Under anteroposterior fluoroscopy, the MPA2 catheter is advanced through the right atrium, right ventricle, pulmonary artery, and PDA into the descending aorta, and the exchange wire is placed below the diaphragm. Subsequently, the distal end of the hole

catheter is advanced, either directly or under wire guidance, through the PDA into the descending aorta. Then, a hand-push contrast agent is used or switched to a pigtail catheter for descending aortic angiography. Subsequently, an exchange wire is used to position the occluder in place following conventional methods. After the occluder is deployed, the delivery sheath is retracted to the proximal pulmonary artery, the morphology of the PDA occluder is observed under fluoroscopy, a pull test is performed, and if necessary, hand-push contrast agent is used to check for residual shunting and assess whether the occluder affects the opening of the left pulmonary artery. However, during the procedure, additional observations of the position of the occluder and residual shunting may be required using bedside (Transesophageal Echocardiography) TTE, as well as a measurement of the blood flow acceleration at the end of the descending aorta. Once satisfactory, the occluder is released.

Statistical Analysis

Statistical analysis was performed using SPSS 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as the mean ± standard deviation or median (interquartile range), while categorical variables are presented as frequencies and percentages. Procedural success rates, complication rates, and long-term outcomes were compared between the two closure routes using appropriate statistical tests, including *t*-tests for continuous variables and chi-square tests for categorical variables. A p-value < 0.05 was considered statistically significant.

Results

Table 1 shows that there are no statistically significant differences between the CA and SV groups in terms of age, weight, gender distribution, duct size, duct length, LVEDD, PA diameter, LVEF, pulmonary artery systolic pressure (PASP), cardiothoracic ratio, and the presence of arrhythmia (all $p > 0.05$).

Table 2 shows that the initial successful closure rate was similar between the CA and SV groups (96.9% vs. 95.1%, $p = 0.634$). In the CA group, the interventional occlusion could not be completed in three cases, which were subsequently converted to surgical procedures. Comparatively, four cases in the SV group were also unable to complete the interventional occlusion and were converted to surgical procedures. The CA group had a significantly longer operating time compared to the SV group (60.3 ± 18.3 vs. 42.6 ± 10.9 minutes, $p < 0.001$). Length of stay was significantly shorter in the SV group compared to the CA group (26.3 ± 8.6 vs. 19.8 ± 7.6 hours, $p < 0.001$). There were no statistically significant differences in the detectable shunting and audible murmur in the echocardiogram between the CA and SV groups ($p > 0.05$). The cost of the procedure was significantly lower in the SV group compared to the CA group (3194.4 ± 213.1 vs. 4583.3 ± 325.5 USD, $p < 0.001$). The total complication rate was significantly higher in the CA group compared to the SV group (4.2% vs. 1.2%, $p < 0.001$). Preoperative preparation dose and X-ray fluoroscopy time were significantly lower in the SV group compared to the CA group ($p < 0.001$ and $p = 0.002$, respectively). Radiation dose was also significantly lower in the SV group compared to the CA group ($p = 0.010$).

Follow-up Outcomes

A total of 171 patients underwent a follow-up until January 2024. Seven patients who had incomplete closure by transcatheter Amplatzer occlusion did not enroll in the follow-up evaluation. The follow-up period ranged from 5 to 18 years (mean, 10.2 ± 1.1 years) in the CA group and from 5 to 18 years (mean, 10.4 ± 2.1 years) in the SV group. Tables 3,4 show no significant differences in follow-up time, death rate, late recanalization, and left ventricular overload between the CA and SV groups (all $p > 0.05$). Both preoperative and postoperative LVEDD and PA showed significant improvements within each group (all $p < 0.05$). Meanwhile, no statistically significant differences were observed in the postoperative LVEDD and PA between the CA and SV groups ($p > 0.05$).

Discussion

PDA is one of the common congenital vascular anomalies in children. Normally, the PDA anatomically closes within the first three months after birth. However, if the ductus arteriosus remains open after birth, it can cause left-to-right shunting, leading to a series of complications such as congestive heart failure [14–16]. In severe cases, PDA may even be life-threatening. Therefore, timely intervention for PDA closure is of significant clinical importance. Interventional closure therapy for PDA offers advantages, including fewer complications and shorter recovery times, gradually replacing traditional open surgical ligation for PDA closure [17]. This study aimed to compare our experience with the CA technique to that of the SV technique.

Therefore, this study compared the long-term clinical outcomes and costs of two interventional closure routes for treating PDA in children. Our investigation focused on the CA and SV approaches. These findings shed light on the efficacy, safety, and economic implications of these approaches in pediatric patients with PDA.

In terms of demographic and preoperative clinical conditions, no statistically significant differences were observed between the CA and SV groups. This suggests that both approaches were comparable in terms of patient characteristics and baseline conditions. The initial successful

Table 1. Demographics and preoperative clinical conditions in the CA and SV groups.

Indices	CA group (n = 96)	SV group (n = 82)	*p*-value
Age (years)	10.8 ± 5.9 (1–18)	11.1 ± 4.4 (1–20)	0.678
Weight (kg)	22.3 ± 8.3 (10–45)	24.5 ± 9.7 (11–50)	0.312
Gender (M/F)	46/50	40/42	0.708
Duct size (mm)	6.8 ± 2.9 (2–14.0)	6.6 ± 3.3 (2–14.0)	0.783
Duct length (mm)	6.3 ± 2.2 (3.5–11.3)	6.8 ± 3.0 (2.5–12.0)	0.462
LVEDD (mm)	40.1 ± 12.3 (23–47)	41.3 ± 13.6 (25–52)	0.549
PA (mm)	18.3 ± 5.2 (10–30)	19.5 ± 6.2 (9–30)	0.429
LVEF (%)	58.7 ± 8.1 (47–66)	59.6 ± 10.6 (50–67)	0.691
PASP (mmHg)	39.8 ± 15.2 (19–70)	40.3 ± 13.8 (17–76)	0.879
Cardiothoracic ratio	0.54 ± 0.17 (0.50–0.66)	0.53 ± 0.15 (0.50–0.65)	0.582
Arrhythmia (%)	10.1	9.8	0.927

Note: The CA group refers to the group undergoing the conventional arteriovenous approach; the SV group refers to the group undergoing the single-view approach; LVEDD, left ventricular end-diastolic diameter; PA, pulmonary artery diameter; LVEF, left ventricular ejection fraction; PASP, peak pulmonary artery systolic pressure.
A *p*-value less than 0.05 indicates statistical significance.

Table 2. Technical indices, cost, and acute complications in the CA and SV groups.

Indices	CA group (n = 96)	SV group (n = 82)	*p*-value
Technical indices			
Initial successful closure: n (%)	93 (96.9)	78 (95.1)	0.634
Operating time (min)	60.3 ± 18.3	42.6 ± 10.9	<0.001
Length of stay (hours)	26.3± 8.6	19.8 ± 7.6	<0.001
Detectable shunting in the echocardiogram	1 (1.0)	1 (1.2)	1.000
Audible murmur	4 (4.2)	3 (3.7)	0.815
Conversion to subsequent procedure to close PDA	3 (3.1)	4 (4.9)	0.562
Cost ($)	4583.3 ± 325.5	3194.4 ± 213.1	<0.001
Acute complications: n (%)			
Death	0 (0)	0 (0)	
Major bleeding	0 (0)	0 (0)	
Blood transfusion	0 (0)	0 (0)	
Recurrent laryngeal dysfunction	0 (0)	0 (0)	
Pleural effusion	0 (0)	0 (0)	
Systemic infection	0 (0)	0 (0)	
Infectious endocarditis	0 (0)	0 (0)	
Thromboembolism	0 (0)	0 (0)	
Hemolysis	0 (0)	0 (0)	
Dislodged occluder	0 (0)	0 (0)	
Femoral artery and vein injury	4 (4.2)	1 (1.2)	
Total complications (%)	4 (4.2)	1 (1.2)	<0.001
Preparation dose (mL)	40.2 ± 2.1	21.7 ± 3.2	<0.001
X-ray fluoroscopy time (min)	21.2 ± 3.5	18.0 ± 6.6	0.002
Radiation dose (mGy)	218.23 ± 31.56	176 ± 63.2	0.010

Note: The CA group refers to the group undergoing a conventional arteriovenous approach; the SV group refers to the group undergoing a single-view approach. PDA, patent ductus arteriosus.

closure rate was similar between the CA and SV groups, indicating that both methods were effective in achieving PDA closure. However, it is noteworthy that a small proportion of cases in both groups required conversion to surgical procedures due to technical challenges. The CA group had a significantly longer operating time compared to the SV group, which may be attributed to the complexity of CA. Some possible complications include significant bleeding, blood transfusion, recurrent laryngeal dysfunction, pleural effusion, systemic infection, infectious endocarditis, thromboembolism, hemolysis, and occluder displacement, which were not observed in this study. A small

Table 3. Follow-up outcomes in the CA and SV groups.

Indices	CA group (n = 93)	SV group (n = 78)	*p*-value
Follow-up time: years (range)	10.2 ± 1.1 (5–18)	10.4 ± 2.1 (5–18)	0.449
Death: n (%)	0 (0)	0 (0)	1.000
Late recanalization: n (%)	0 (0)	0 (0)	1.000
Left ventricular overload: n (%)	0 (0)	0 (0)	1.000

Note: The CA group refers to the group undergoing the conventional arteriovenous approach; the SV group refers to the group undergoing the single-view approach.

Table 4. Pre- and postoperative LVEDD and PA in the CA and SV groups.

	LVEDD		PA	
	CA group (n = 93)	SV group (n = 78)	CA group (n = 93)	SV group (n = 78)
Preoperative	40.1 ± 12.3	41.3 ± 13.6	18.3 ± 5.2	19.5 ± 6.2
Postoperative	36.5 ± 11.4[a]	35.2 ± 12.1	15.8 ± 3.2[a]	16.3 ± 3.3
p-value	0.003	0.001	0.002	0.001

Note: The CA group refers to the group undergoing the conventional arteriovenous approach; the SV group refers to the group undergoing the single-view approach; LVEDD, left ventricular end-diastolic diameter; PA, pulmonary artery diameter.

a: The difference in postoperative LVFDD and PA between the CA and SV groups is not statistically significant ($p > 0.05$).

number of patients experienced femoral artery and vein injuries, which are consistent with findings from other studies [18–20]. The SV group had a shorter length of stay, suggesting faster recovery and shorter hospitalization duration compared to the CA group. The difference in hospitalization duration between the two groups may be attributed to the following factors: The SV technique significantly reduces surgical trauma by requiring only a single venous puncture (5–7 F sheath), as opposed to the dual arterial–venous access needed for the CA technique (6–8 F + 5–7 F), consequently decreasing vascular injury rates (4.2% vs. 1.2%). This results in reduced postoperative pain and accelerated recovery—CA patients require 12 hours of bed rest to prevent femoral artery bleeding. In contrast, SV patients achieve mobility within just 4 hours. Importantly, the 4.2% vascular complication rate observed in the CA group (requiring management of hematomas/pseudoaneurysms) prolongs hospitalization and necessitates additional Doppler ultrasound examinations. In contrast, the minimal 1.2% venous complication rate noted in the SV group typically resolves following simple compression, obviating the need for supplementary imaging.

The cost analysis revealed that the SV group incurred significantly lower procedural costs compared to the CA group. This finding suggests that the SV approach may offer advantages in terms of procedural efficiency and resource utilization. The SV group had lower costs primarily due to greater procedural efficiency and resource utilization. The CA approach necessitates the use of snare devices to establish an arteriovenous circuit, with an average consumption of 1.2 units per case, whereas the SV approach completely eliminates this expense. Additionally, complications in the CA group—particularly femoral artery injuries (with a 4.2% incidence)—promote increased costs per case, including vascular ultrasound examinations, additional treatment expenses, and extended nursing hours. The longer hospital stays in the CA group further contributed to higher expenditures, with additional costs for bed occupancy, nursing care, and medications. In contrast, the SV group allows patients to ambulate within 6 hours post-procedure, significantly reducing rehabilitation and nursing costs. Additionally, the total complication rate was significantly higher in the CA group compared to the SV group. Our findings regarding the simplified venous approach align with existing literature. Thanopoulos *et al*. [21] demonstrated comparable success rates (94.7%) with the venous-only approach, while reporting significantly shorter procedure times (38.5 ± 12.3 min) and hospital stays (1.2 ± 0.5 days) compared to conventional methods. Similarly, a multicenter study by Wei *et al*. [22] involving 312 cases confirmed the non-inferiority of the venous approach in terms of technical success (96.2% vs. 97.8%, $p = 0.34$), while highlighting its advantages in terms of reduced vascular complications (1.9% vs. 6.4%, $p = 0.02$). The economic benefits we observed are further supported by Xiong *et al*. [23], whose cost analysis revealed 28.6% lower hospitalization costs with the venous approaches (3542 vs 4962), primarily attributed to reduced consumable expenses and shorter recovery times. These consistent findings across multiple studies strengthen the evidence base for adopting the SV approach as the first-line therapy for suitable PDA anatomies.

Regarding follow-up outcomes, no cardiac deaths occurred in either group, thus confirming the safety of both

techniques during the follow-up period. Similar results have been reported by other authors [24,25]. Moreover, no significant differences were noted in the follow-up time, mortality rates, late recanalization, or left ventricular overload between the CA and SV groups. This suggests that both approaches resulted in comparable long-term clinical outcomes. Furthermore, both preoperative and postoperative improvements in LVEDD and PA were observed within each group, with no significant differences between the CA and SV groups in postoperative LVEDD and PA.

In conclusion, our study highlights the importance of considering both clinical outcomes and costs when selecting the optimal intervention for treating PDA in children. While both CA and SV approaches demonstrate efficacy in achieving closure, the choice between the two should consider factors such as procedural complexity, resource utilization, and cost-effectiveness. For cases where the catheter cannot be smoothly inserted into the descending aorta from the pulmonary artery, it is recommended to use the CA approach for interventional treatment. This involves establishing an arteriovenous track using a snare catheter, enabling the delivery sheath to reach the intended site for completing the PDA closure procedure. Direct venous PDA closure is a safe and effective procedure, with lower complication rates and associated costs. As operator intervention techniques improve, their frequency of utilization is expected to increase gradually. This study has several limitations that should be considered: Potential era effect: Given the extended time frame of the study, evolving techniques and experience over the years may have introduced some bias in the outcomes. Operator variability: Although all operators were experienced, individual differences in technique or preference were not formally analyzed. Future studies should include assessments of operator variability and time-stratified subgroup analyses. Technological progress: As interventional techniques continue to advance (e.g., improved imaging guidance, newer devices), the SV approach may demonstrate even better outcomes. Continued evaluation is needed as practice evolves. Sample size and follow-up: Although our findings are robust, larger multicenter studies with longer-term follow-up would further validate these results and provide a more informed basis for clinical decision-making regarding pediatric PDA closure.

Conclusions

The study confirms that the simple venous (SV) approach for PDA closure in children is as effective as the conventional arteriovenous (CA) method but offers significant advantages, including shorter procedure times, reduced hospital stays, lower complication rates, and decreased costs. These findings support the SV approach as a safer and more cost-effective option for suitable pediatric patients, with comparable long-term outcomes. Further research is recommended to validate these results in broader populations.

Availability of Data and Materials

The data supporting the findings of this study are not publicly available due to the inclusion of information that could compromise the privacy of participants under 18 years of age. However, they are available from the corresponding author upon reasonable request.

Author Contributions

QK and HC conceived and designed the study. GW, QX, JB, FZ, JH, JL and LY collected and analyzed the data. QK and HC wrote the main manuscript text. All authors reviewed and approved the final manuscript. All authors have participated sufficiently in the work and agreed to be accountable for all aspects of the work. All authors contributed to editorial changes in the manuscript.

Ethics Approval and Consent to Participate

The study was carried out in accordance with the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Fujian Provincial Hospital (Protocol No. K2025-01-008). Written informed consent was obtained from the parents or legal guardians of all participants involved in the study. All procedures were performed with respect for the rights and confidentiality of the patients.

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Conflict of Interest

The authors declare no conflict of interest.

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