ORIGINAL ARTICLE

VENOUS-ONLY TRANSCATHETER CLOSURE: A SAFE AND EFFECTIVE STRATEGY FOR PATENT DUCTUS ARTERIOSUS

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Objectives: This study aimed to assess the feasibility and effectiveness of transcatheter device closure of patent ductus arteriosus (PDA) exclusively through an isolated venous route.

Methodology: A retrospective descriptive study was conducted at the Rawalpindi Institute of Cardiology. Patient data from 2019 to 2023 undergoing PDA closure using transcatheter devices were analyzed. PDA diagnosis was established via echocardiography, and the procedure was performed solely through a venous line under fluoroscopy, omitting the traditional method of using both arterial and venous lines.

Results: A total of 212 patients underwent transcatheter PDA closure through a venous-only route, with ages ranging from 6 months to 14 years. The mean weight was 10.07 kg (range: 5 kg to 27 kg, SD 4.43). The average procedure time was 30 ± 10.3 minutes (range: 15.0 to 65 minutes), and fluoroscopy time was 5.4 ± 3.18 minutes (range: 2.1 to 19 minutes). Immediate closure was achieved in all patients, with no residual leaks or device embolization observed. Additionally, there were no reported complications such as arrhythmia, vascular access issues, or significant blood loss. No cases of aortic or pulmonary stenosis were identified, and no deaths occurred. All patients were discharged within 48 hours post-procedure.

Conclusion: Transcatheter closure of PDA exclusively through the venous route, without the use of an arterial line, demonstrates itself as an effective and safe method for PDA closure.

Keywords: Transcatheter closure, Patent ductus arteriosus, venous route, congenital heart disease

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INTRODUCTION

Patent ductus arteriosus (PDA) stands as a significant component, comprising approximately 10% of congenital heart anomalies, posing substantial challenges in pediatric cardiology.[1] The closure of PDA holds paramount importance in mitigating the risks associated with heart failure, Eisenmenger syndrome, recurrent chest infections, and infective endocarditis. While surgical closure has long been regarded as a safe and effective approach, it is not without its inherent risks and morbidities, particularly those related to anesthesia and surgery.[2]

Since its inception in 1967, transcatheter PDA closure using duct occluders has emerged as a viable alternative, demonstrating both safety and efficacy.[3] Traditionally, this procedure necessitates both arterial and venous access.[4] However, complications stemming from femoral artery access, such as bleeding and thrombosis necessitating anti-thrombolytic therapy, present significant challenges, particularly in smaller children with lower body weights. Additionally, the conventional technique often results in prolonged procedure and fluoroscopy times, delayed hospital discharges due to arterial complications, and increased utilization of contrast dye.[5]

Several studies have shed light on the isolated venous approach, suggesting its non-inferiority compared to the conventional technique. Despite its potential advantages, research on the experience of this technique for PDA device closure remains limited, specifically in our region, Pakistan.[6]

The current study aims to address this gap by evaluating the effectiveness and safety of ductus arteriosus closure utilizing the venous route. By

focusing on the outcomes of this innovative approach, this study endeavors to provide cardiologists with valuable insights to enhance PDA device occlusion beyond conventional routes. Ultimately, the findings of this study are poised to contribute to the optimization of clinical practices and improve patient outcomes in the management of PDA.

METHODOLOGY

Study Design: This study employed a retrospective descriptive design to investigate the outcomes of PDA (Patent Ductus Arteriosus) device occlusion. Retrospective data from patients spanning five years (2019-2023) was collected and analyzed.

Setting: The study was conducted at the Rawalpindi Institute of Cardiology, providing a specialized environment for cardiac care and interventions. All procedures were performed in accordance with institutional protocols.

Participants: A total of 212 patients were included in the study. The inclusion criteria encompassed patients undergoing PDA device occlusion exclusively through the isolated venous route. Exclusion criteria were established for patients requiring arterial access for device occlusion and those with severe pulmonary hypertension or large PDAs measuring more than 6mm narrow point.

Variables: Variables of interest included demographical profile, gender predisposition, PDA size, size of device, and complications associated with the procedure. Additionally, echocardiographic findings such as PDA diameter and length, Krichenko classification, shunting, evidence of pulmonary hypertension, and left ventricular volume overload were assessed.

Data Sources/Measurement: Data was collected from medical records, including symptoms, signs, and echocardiographic findings of patients. Clinical diagnosis of ductus arteriosus was confirmed by echocardiography in all cases. Echocardiographic measurements of PDA, including diameter and length, were evaluated, alongside the type of PDA according to Krichenko classification, shunting, evidence of pulmonary hypertension, and left ventricular volume overload.

Bias: Efforts were made to minimize bias by adhering to strict inclusion and exclusion criteria, utilizing standardized procedures for data collection and analysis, and ensuring consistency in the application of diagnostic and therapeutic interventions.

Study Size: The sample size comprised 212 patients, providing a robust dataset for analysis and interpretation of outcomes related to PDA device occlusion.

Quantitative Variables: Continuous variables were analyzed as mean and percentages, while categorical variables were assessed through frequencies. This comprehensive approach facilitated a detailed examination of the demographic characteristics, procedural parameters, and clinical outcomes associated with PDA device occlusion.

Statistical Methods: Data analysis was performed using SPSS 19 statistical software. Descriptive statistics were utilized to summarize the demographic profile, gender predisposition, PDA size, size of device, and complications. Continuous variables were analyzed using means, while categorical variables were assessed using frequencies. This statistical approach allowed for a comprehensive evaluation of the study variables and their associations.

RESULTS

Participants: Among the 572 patients who underwent PDA device occlusion during the study period, 212 patients underwent PDA transcatheter device occlusion exclusively through the venous route. The gender distribution included 76 male and 136 female patients, with ages ranging from 6 months to 14 years and a mean age of 32.9 months. Body weights ranged from 5 kg to 27 kg, with a mean weight of 10.07 kg (standard deviation 4.43).

Descriptive Data: The average procedure time was 30 minutes, with a range of 15.0 to 65 minutes, while the fluoroscopy time was 5.4 minutes, ranging from 2.1 to 19 minutes. Type A PDA was predominant, observed in 93.8% (n=199) of cases, followed by type B in 2.3% (5) and type C in 3.78% (8) of cases. The sizes of occluders varied from 3.5/5 mm to 10/8 mm. The mean pulmonary artery pressure was 22 mmHg, ranging from 13 to 50 mmHg. Occlutech, Memopart, and Life Tech PDA occluders were utilized in the procedures.

Outcome Data: Immediate closure was successfully achieved in all patients, with no immediate complications reported, such as residual leaks or device embolization. Additionally, there were no instances of arrhythmia, vascular access issues, or significant blood loss. The study did not identify any evidence of aortic or pulmonary stenosis, and no patient fatalities occurred during or immediately following the procedure.

Main Results: The main findings indicate the safety and efficacy of PDA transcatheter device occlusion exclusively through the venous route. The procedure was associated with successful immediate closure and low incidence of complications, demonstrating its feasibility as a treatment option for PDA in pediatric patients. These results underscore the importance of this minimally invasive approach in achieving favorable outcomes and reducing the need for surgical intervention. Additionally, the absence of adverse events highlights the procedural reliability and favorable post-operative course, with all patients discharged within 48 hours post-procedure.

Table 1: Descriptive, demographics, and clinical characteristics of the patients

Characteristics	Summary
Total (N)	**212**
Gender	
Male	76 (35.8%)
Female	136 (64.2%)
Type of PDA	
A	199 (93.9%)
B	5 (2.4%)
C	8 (3.8%)
Device size	
3.5/5	3 (1.4%)
4/6	42 (19.8%)
5/7	71 (33.5%)
6/8	65 (30.7%)
8/10	18 (8.5%)
10/12	2 (0.9%)
Transthoracic echocardiography	212 (100%)
Anesthesia: general anesthesia	212 (100%)
Complication: None	212 (100%)
Weight (kg)	10.1 + 4.5
Age (months)	32.9 + 33.3
Procedure time (min)	30.1 + 9.9
Fluoroscopy time (min)	5.5 + 3.2

DISCUSSION

Transcatheter PDA closure stands as a cornerstone in the armamentarium of pediatric cardiology, offering a safe and effective alternative to surgical intervention with minimal morbidity and mortality.[7] However, like any medical procedure, it is not devoid of potential complications. These may encompass device embolization, residual leaks, pulmonary artery stenosis, narrowing of the descending aorta, and hemolysis.[8] Notably, vascular complications, including loss of femoral pulse, represent one of the most significant concerns, particularly in younger children with lower body weights, necessitating antithrombotic therapy with inherent risks.[9]

The conventional approach to PDA device occlusion typically involves both arterial and venous access, with arterial access serving various diagnostic and procedural purposes. However, this approach is not without drawbacks, as evidenced by the high incidence of arterial complications reported in previous studies.[10] Our study adopts a novel approach by exclusively utilizing venous access, thereby mitigating the risk of vascular complications associated with arterial access.

Our findings align with previous literature, demonstrating a notable reduction in vascular complications compared to conventional techniques.[9-11] Notably, we did not observe any instances of bleeding or loss of femoral pulse in our study cohort. By eschewing arterial access, we achieved shorter procedure and fluoroscopy times, consequently reducing the need for excessive contrast dye, which is particularly advantageous in pediatric patients.

Despite the success of the venous-only approach, meticulous morphological assessment of the PDA remains imperative to mitigate the risk of complications.[12] Precise sizing of the ductus on echocardiography is crucial, as inadequate sizing can lead to procedural challenges and the need for device upsizing, potentially prolonging the procedure and increasing technical complexity.[13,14] Our study encountered cases where precise duct sizing was challenging due to duct morphology, highlighting the importance of careful pre-procedural assessment.

Furthermore, the isolated venous technique may facilitate earlier discharge, potentially enhancing patient satisfaction and optimizing healthcare resource utilization.[15] Contrary to some previous findings,[16,17] our study did not observe a significant increase in procedural or fluoroscopic times, underscoring the feasibility and efficiency of this approach.

LIMITATION

It's important to acknowledge the limitations of our study. Specifically, the exclusion of cases with PDA larger than 6mm and those with pulmonary hypertension may limit the generalizability of our findings to a broader patient population. Additionally, the retrospective nature of the study design may introduce biases and limitations inherent to such methodologies. Further prospective studies with larger sample sizes are warranted to validate our findings and explore the long-term outcomes associated with this innovative approach to PDA closure.

CONCLUSION

Our study adds to the growing body of evidence supporting the efficacy and safety of transcatheter PDA closure exclusively through the venous route. By eschewing arterial access, we mitigated the risk of vascular complications, resulting in shorter procedure and fluoroscopy times, and reducing the need for

excessive contrast dye. These findings underscore the feasibility and efficiency of the isolated venous approach in PDA device occlusion. Furthermore, while the venous-only technique presents certain challenges, such as the need for precise morphological assessment of the PDA and potential difficulties in duct sizing, our study demonstrates that these hurdles can be effectively managed with careful pre-procedural planning and utilization of echocardiography during the procedure.

AUTHORS' CONTRIBUTION

SZ and MNK: Concept and design, data acquisition, interpretation, drafting, final approval, and agree to be accountable for all aspects of the work NAS, KN, IJB, and SR: Data acquisition, interpretation, drafting, final approval and agree to be accountable for all aspects of the work.

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