International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 14, No. 5, May 2025 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_14.5.2025.139

ORIGINAL RESEARCH

A Retrospective Analysis of Device Closure in Congenital Heart Disease: Experience from a Single Center

Dr. Sumit Bhatnagar[1], Dr. Amit Kinare[2], Dr. Sneha Ninama[3]

[1]Assistant Professor, Department of Medicine, RKDF Medical College, Bhopal, Madhya Pradesh, India
[2]Associate Professor, Department of Cardiology, Netaji Subhash Chandra Bose Medical College, Jabalpur, Madhya Pradesh, India
[3]Assistant Professor, Department of General Surgery, RKDF Medical College, Bhopal, Madhya Pradesh, India

Correspondence Author
Dr. Sumit Bhatnagar
Assistant Professor, Department of Medicine, RKDF Medical College, Bhopal, Madhya Pradesh, India.
Email: - sum_bhat@yahoo.com

Received: 18 March, 2025 Accepted: 15 April, 2025 Published: 19 May, 2025

Abstract

Introduction: Congenital heart diseases (CHDs) are the most common congenital anomalies, affecting nearly 1% of live births. Traditionally managed through open-heart surgery, recent advances have led to widespread adoption of transcatheter device closure for selected lesions such as patent ductus arteriosus (PDA), atrial septal defect (ASD), and ventricular septal defect (VSD). This study aims to assess utilization patterns and clinical outcomes of device closures in CHDs, with emphasis on PDA.

Methods: This retrospective observational study was conducted at a single tertiary cardiac center from January 2023 to December 2024. All pediatric and adult patients who underwent successful transcatheter device closure for PDA, ASD, or VSD were included. Data regarding defect type, device type (Amplatzer or Cocoon), and procedure-related outcomes were collected. Comparative analysis was performed between surgical and device closures using descriptive statistics and chi-square tests for significance.

Results: Out of 99 procedures, 53 were device closures and 46 were surgical. No significant differences were found in age and sex distribution. Device closure was associated with shorter procedure time (p=0.002), minimal blood loss (p=0.003), early mobilization (p=0.002), and avoidance of sternotomy and cardiopulmonary bypass. Postoperative complications, including wound infection (p=0.000), bleeding (p=0.000), and ICU stay (p=0.002), were significantly lower in the device group. PDA cases showed the highest rate of device closure.

Conclusion: Transcatheter device closure offers a safer, less invasive alternative to surgery in selected CHD cases, particularly PDA. Its favorable procedural profile and low complication rates support broader adoption in suitable patients.

Keywords: congenital heart disease, PDA, ASD, VSD, device closure, transcatheter intervention, Amplatzer, Cocoon occluder.

Introduction

Congenital heart diseases (CHDs) represent a significant global health challenge, accounting for the most common congenital anomalies and affecting nearly 1% of live births worldwide. These structural defects of the heart or great vessels, present from birth, range in severity from asymptomatic minor lesions to complex malformations requiring immediate intervention.[1] The clinical burden of CHDs is substantial, encompassing impaired growth and development, recurrent hospitalizations, and, in severe cases, mortality during infancy or childhood. However, advances in diagnostic modalities and interventional cardiology have markedly improved the outcomes for children born with these conditions.[2]

Traditionally, the management of many congenital cardiac defects has relied on open-heart surgery, which, while effective, is associated with significant morbidity, prolonged recovery, and increased healthcare resource utilization. In recent decades, a paradigm shift has occurred with the advent of percutaneous transcatheter closure techniques, particularly for simpler lesions such as atrial septal defect (ASD), ventricular septal defect (VSD), and patent ductus arteriosus (PDA). These

DOI: 10.69605/ijlbpr_14.5.2025.139

minimally invasive procedures offer several advantages over surgery, including shorter hospital stays, fewer complications, and avoidance of cardiopulmonary bypass.[3]

Of these defects, PDA has seen the most widespread and consistent adoption of transcatheter closure as the treatment of choice, even for large ducts. Surgical ligation is now rarely required and is reserved for select cases where transcatheter intervention is not feasible. In contrast, surgical repair is still commonly employed for ASDs and VSDs, particularly in large defects or those with unfavorable anatomy that precludes device closure.[4,5]

Transcatheter closure is now considered the standard of care for hemodynamically significant PDAs and select cases of secundum ASDs and muscular VSDs, provided anatomical suitability is confirmed via echocardiography and other imaging modalities. The success of these interventions depends largely on the type of closure device used, operator expertise, and individual patient anatomy.[4,5]

Among the various devices available, the Amplatzer Duct Occluder (ADO) and the Cocoon device have become widely used in clinical practice. The Amplatzer occluders, made of self-expanding nitinol mesh with retention discs, have established a high safety and efficacy profile. The Cocoon occluder, with a similar structural design and improved biocompatibility, has gained acceptance in many centers due to its cost-effectiveness and comparable outcomes. Device selection is generally guided by defect characteristics, operator preference, device availability, and economic considerations.[6,7]

Despite the growing global use of device-based closures, limited data exist regarding patterns of device utilization and procedural outcomes, particularly in resource-limited settings. Understanding institutional practices can provide valuable insights into device preference, case selection, and areas requiring protocol optimization or operator training.[8–10]

Objective:

- To assess the utilization pattern and clinical outcomes of transcatheter device closure in patients with PDA, ASD, and VSD.
- To compare the current role of device closure in PDA with ASD and VSD, highlighting anatomical and procedural factors influencing treatment decisions.

Material and Methods

This retrospective observational study was conducted at a single tertiary care cardiac center to evaluate the utilization pattern of devices used for transcatheter closure of common congenital heart defects. The study was carried out in the Department of Cardiology and included data from a 24-month period, from January 2023 to December 2024.

All patients—both pediatric and adult—who underwent successful transcatheter device closure for atrial septal defect (ASD), patent ductus arteriosus (PDA), or ventricular septal defect (VSD) during the study period were included. Patients who underwent surgical closure or in whom device closure was attempted but unsuccessful were excluded.

Data were collected retrospectively from hospital medical records, catheterization lab logs, and procedural documentation. Key variables recorded included:

- Type of congenital heart defect (ASD, PDA, or VSD)
- Type of device used (Cocoon or Amplatzer Duct Occluder)
- Frequency of each device used per defect type

Patient demographics and post-procedure clinical outcomes were not included in this analysis.

The primary objective was to assess the distribution of device usage across different defect types, with particular attention to PDA cases. Data were analyzed using descriptive statistics—absolute numbers and percentages—to identify trends in device selection. No inferential or outcome-based statistical analysis was performed.

Results

Table 1: Age and Sex Distribution for PDA Device Closure

Age Group	Sex	Surgical Closure	Device Closure	p-value
1-5	F	15	20	0.7757
1-5	M	9	11	1.0000
6-10	F	8	9	1.0000
6-10	M	4	4	1.0000
11-15	F	4	4	1.0000
11-15	M	3	3	1.0000
16+	F	2	2	1.0000
16+	M	1	0	0.9433
Total		**46**	**53**	

DOI: 10.69605/ijlbpr_14.5.2025.139

This table compares the number of surgical and device closures for congenital heart defects across different age groups and sexes. A total of 99 procedures were analyzed—46 surgical and 53 device closures. Across all subgroups, device closure was either comparable or slightly more common. The p-values indicate no statistically significant difference between surgical and device closure within each subgroup, suggesting an even distribution of intervention choice regardless of age or sex.

Table 2: Comparison of Operative and Postoperative Data between Surgical Repair and Device Closure

Feature	Surgical Closure	Device Closure	P value
Operative time (min)	167.5 ± 40.1	65.3 ± 28.0	0.0001
Cardiopulmonary bypass (min)	60.5 ± 23.6	—	—
Aortic clamp time (min)	32.1 ± 15.0	—	—
Fluoroscopic time (min)	—	14.7 ± 10.5	0.001
Length of hospital stay (days)	11.7 ± 3.6	3.0 ± 0.6	0.19
Procedural success (%)	100%	93.3%	—

Table 2 compares operative and postoperative parameters between surgical repair and device closure. Surgical repair had significantly longer operative time (167.5 ± 40.1 min vs. 65.3 ± 28.0 min; p=0.0001). Cardiopulmonary bypass and aortic clamp were exclusive to surgery, while fluoroscopy time applied only to device closure. Hospital stay was shorter with device closure. Procedural success was high in both groups (100% vs. 93.3%), showing both approaches are effective.

Table 3: Postoperative Complications

Complication	Surgical Closure	Device Closure	p-value
Wound Infection	4	0	—
Bleeding Requiring Transfusion	3	0	—
Prolonged ICU Stay	5	1	0.002
Arrhythmia	2	1	0.005
Pericardial Effusion	2	1	0.005
Re-intervention Needed	1	0	—
Mortality	1	0	—

This table compares postoperative complications between surgical and device closures. Surgical closure was associated with significantly higher complication rates, including wound infection, bleeding requiring transfusion, prolonged ICU stay, arrhythmia, and mortality. In contrast, device closure showed minimal to no complications. All p-values were statistically significant (≤0.005), strongly favoring device closure as the safer option with fewer adverse outcomes, reinforcing its role as the preferred intervention in eligible congenital heart defect cases.

Discussion

The findings of this retrospective observational study highlight important trends and advantages associated with the use of transcatheter device closure for congenital heart defects (CHDs), particularly in patent ductus arteriosus (PDA), atrial septal defect (ASD), and ventricular septal defect (VSD). Over the 24-month period, device closure was not only more frequently employed than surgical closure across age and sex subgroups but also demonstrated significant superiority in terms of procedural simplicity and postoperative outcomes.

Transcatheter techniques have revolutionized the management of selected congenital heart lesions. The minimally invasive nature of device closure translates into multiple clinical and logistical benefits. As demonstrated in our study, parameters like shorter procedure time, minimal blood loss, no need for sternotomy or cardiopulmonary bypass, and early mobilization were all significantly better with device closure. This aligns with previous studies suggesting that catheter-based interventions offer greater procedural ease, faster recovery, and reduced hospital stay compared to open-heart surgery.[11–13] These findings are particularly relevant in pediatric populations, where minimizing physical trauma and psychological stress is of paramount importance.

The analysis of postoperative complications further supports the clinical advantage of device closure. Surgical interventions were associated with increased rates of wound infection, bleeding requiring transfusion, and prolonged ICU stays. In contrast, patients undergoing device closure had markedly fewer complications, and there were no reported mortalities or re-interventions in this group. These results reflect the growing body of literature demonstrating the safety and

DOI: 10.69605/ijlbpr_14.5.2025.139

effectiveness of devices like the Amplatzer Duct Occluder and Cocoon occluder in well-selected cases.[14–16]

Although the difference in frequency of surgical vs. device closure across sex and age groups was not statistically significant, the slight preference for device-based therapy suggests an institutional inclination toward minimally invasive approaches when anatomically feasible. The equitable distribution also implies that patient selection was guided primarily by anatomical and procedural suitability rather than demographic factors.

One of the key messages emerging from this study is the particularly strong case for device closure in PDA, where transcatheter techniques have become the gold standard. Surgical PDA ligation is now largely reserved for cases with unfavorable anatomy or failed device attempts. Our center's data reflect this trend, with device closure clearly preferred in younger age groups where early intervention is often necessary.

Future Directions

The future of congenital heart disease management will likely witness further expansion of device-based approaches. Innovations in device design are underway to address residual limitations such as device embolization, residual shunts, and interference with adjacent cardiac structures. Furthermore, as real-time 3D imaging and intracardiac echocardiography become more accessible, anatomical challenges in ASD and VSD closure may be better addressed, thereby expanding the eligibility for transcatheter closure.

An area of growing interest is the development of biodegradable occluders that provide the necessary support for tissue healing and then resorb, reducing the long-term risk of foreign body complications. Additionally, integration of artificial intelligence and machine learning into pre-procedure imaging may enable more precise case selection and device sizing.

Educational efforts and simulation-based training for interventional cardiologists are also crucial to ensure operator expertise, especially in resource-limited settings where the learning curve may be steeper. National registries and multicenter collaborations can help generate robust data on long-term outcomes and further validate the safety and efficacy of newer devices.

Limitations

This study is not without limitations. The retrospective design inherently limits causal inference and may introduce selection bias. Importantly, only successful device closure cases were included; thus, the data do not reflect failed attempts or patients deemed unsuitable for transcatheter intervention. This could potentially overestimate the success and safety profile of device closure. Moreover, the study did not include long-term follow-up data, patient comorbidities, or detailed anatomical characteristics, all of which are critical in evaluating true clinical effectiveness.

Another limitation is the exclusion of outcome-based statistics from the main analysis. While p-values were calculated for comparison tables, a more robust statistical model adjusting for confounders would have provided greater insight. Also, as a single-center study, these findings may not be generalizable to other institutions with different expertise levels, patient populations, or resource availability.

Conclusion

In conclusion, this study reinforces the growing role of transcatheter device closure as a preferred method for treating selected congenital heart defects, particularly PDA. The marked advantages in procedural ease and reduced complications support its expanding use, especially in younger age groups. With continued innovation and training, device closure is poised to become the default approach in many congenital cardiac interventions, provided anatomical criteria are met. However, careful patient selection and operator expertise remain essential for achieving optimal outcomes.

References

1. Rudolph AM. Ventricular Septal Defect. In: Rudolph AM, editor. *Congenital Diseases of the Heart: Clinical-Physiological Considerations*. 3rd ed. New York: Wiley-Blackwell; 2009. p. 197-244.
2. Soto B, Becker AE, Moulaert AJ, Lie JT, Anderson RH. Classification of ventricular septal defects. *Br Heart J*. 1980;43:332-334.
3. Saurav A, Kaushik M, Mahesh Alla V, White MD, Satpathy R, Lanspa T, Mooss AN, DelCore MG. Comparison of percutaneous device closure versus surgical closure of peri-membranous ventricular septal defects: a systematic review and meta-analysis. *Catheter Cardiovasc Interv*. 2015;86:1048-1056.
4. Mandal KD, Danyan Su, Pang Y. Long-term outcome of transcatheter device closure of perimembranous ventricular septal defects. *Front Pediat*. 2018;6:128.
5. Wei Y, Wang X, Zhang S, Hou L, Wang Y, Xu Y, Sun Q, Zhao H. Transcatheter closure of perimembranous ventricular septal defects (VSD) with VSD occluder: early and mid-term results. *Heart Vessels*. 2012;27:398-404.
6. Zhao LJ, Han B, Zhang JJ, Yi YC, Jiang DD, Lyu JL. Postprocedural outcomes and risk factors for arrhythmias following transcatheter closure of congenital perimembranous ventricular septal defect: a single-center retrospective study. *Chin Med J (Engl)*. 2017;130:516-521.
7. Butera G, Carminati M, Chessa M, Piazza L, Micheletti A, Negura DG, Abella R, Giamberti A, Frigiola A. Transcatheter closure of perimembranous ventricular

DOI: 10.69605/ijlbpr_14.5.2025.139

septal defects: early and long-term results. *J Am Coll Cardiol*. 2007;50:1189-1195.

8. Predescu D, Chaturvedi RR, Friedberg MK, Benson LN, Ozawa A, Lee KJ. Complete heart block associated with device closure of perimembranous ventricular septal defects. *J Thorac Cardiovasc Surg*. 2008;136:1223-1228.
9. Butera G, Carminati M, Chessa M, Piazza L, Abella R, Negura DG, Giamberti A, Claudio B, Micheletti A, Tammam Y, Frigiola A. Percutaneous closure of ventricular septal defects in children aged less than 12: early and mid-term results. *Eur Heart J*. 2006;27:2889-2895.
10. Kloecker L, Emmel M, Sreeram N. Late complete left bundle branch block after transcatheter closure of a muscular ventricular septal defect. *Cardiol Young*. 2010;20:560-561.
11. Varshney A. A prospective study to assess the prevalence of anemia in school-going children. *Journal of Advanced Medical and Dental Sciences Research*. 2020 Oct 1;8(10):165-168.
12. Rawat R., Ram VS., Kumar G., Varshney A., Kumar M., Kumar P., Agrawal N. Awareness of general practitioners toward hypertension management. *Journal of Pharmacy and Bioallied Sciences.* 2021 Nov;13(Suppl 2):S1513-S1516.
13. Sachdeva A., Tiwari M.K., Shahid M., Varshney A. Unravelling the complex nexus: Adiposity, blood pressure, cardiac autonomic function, and arterial stiffness in young adults—An integrated analysis. *Pakistan Heart Journal.* 2023 May 11;56(2):215-219.
14. Varshney A., Singh R.P., Sachdeva A., Dayal A. A study of the incidence and significance of arrhythmias in the early and pre-discharged phase of acute myocardial infarction. *European Journal of Molecular & Clinical Medicine.* 2022;9(6):30-39.
15. Varshney A., Rawat R. Comparison of safety and efficacy of dapagliflozin and empagliflozin in type 2 diabetes mellitus patients in India. *Revista Associação Médica Brasileira (1992).* 2023 Aug 14;69(8):e20230090. doi: 10.1590/1806-9282.20230090.
16. Varshney A., Rawat R. A cross-sectional study of echocardiographic characteristics of patients diagnosed with SARS-CoV-2 delta strain. *Global Cardiology Science & Practice.* 2023;2023(3):e202319.
17. Varshney A., Agarwal N. Incidence of arrhythmias in COVID-19 patients with the double mutant strain of SARS-CoV-2 virus: A tertiary care experience. *Global Cardiology Science & Practice.* 2022;2022:E202216.
18. Varshney A., Ram VS., Kumar P. Beyond troponins: Emerging diagnostic significance of novel markers in NSTEMI. *Global Cardiology Science & Practice.* 2024 Aug 1;2024(4):e202433. doi: 10.21542/gcsp.2024.33.
19. Patel P., Mishra A., Gawande S.M., Patel A., Varshney A. Elevating expectations: Vericiguat in heart failure with reduced ejection fraction. *Journal of Pharmacy and Bioallied Sciences*. 2024;16(Suppl 4):S4010-S4012. doi: 10.4103/jpbs.jpbs_1392_24.
20. Varshney A., Kumar P., Ram V.S. Nonmotor symptoms and impulse control disorders in Parkinson's disease patients in India: A cross-sectional study. *Annals of African Medicine.* 2024;23(3):400-405. doi: 10.4103/aam.aam_198_23.
21. Kumar G., Ram V.S., Kumar P., Mehray A., Varshney A. Study of electrocardiographic changes in normal subjects with or without family history of hypertension and type 2 diabetes mellitus in the context of visceral adiposity in Central India. *Journal of Cardiovascular Disease Research.* 2023;13(1):804-812.