DOI: https://doi.org/10.48305/arya.2024.42641.2962

Safety and efficacy of using amplatzer ductal occluder type I and II for peri membranous ventricular septal defect closure: A systematic review

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Review Article

Abstract

BACKGROUND: Ventricular septal defect (VSD) is a common congenital heart defect that affects many individuals. Transcatheter closure has become a successful treatment method. However, certain devices used for closure can lead to life-threatening complications such as complete heart block. This systematic review aimed to assess the efficacy and safety of Amplatzer duct occluders (ADOs) types I and II for closing perimembranous VSDs (pmVSDs).

METHODS: This review followed the PRISMA 2020 guidelines and searched multiple databases for English articles on pmVSD closure using ADO I/II published up to 2022. Relevant keywords were used and the data were categorized to report the incidence of common complications.

RESULTS: The study, which involved 1,691 patients with primary pmVSD and ages ranging from 6 months to 15 years, found that ADO type I had a high success rate with low rates of complete heart block and other complications. ADO type II had a higher rate of severe complications, particularly complete heart block. The overall estimated success rate for device implantation was 97.3%, with only one procedure-related death. The occurrence of complete heart block was 2.3%, and residual shunts were the most frequent complication (4.8%).

CONCLUSION: The findings of this systematic review provide valuable insights into the use of ADO types I and II for closing pmVSDs. Healthcare professionals should be aware of these findings and closely monitor patients who undergo ADO device closure for pmVSDs. Further research is recommended to determine the specific indications for using each type of Amplatzer device in the relevant population.

Keywords: Ventricular Septal Defect; Amplatzer Duct Occluder; Complication Rate

Abbreviations: VSD (Ventricular Septal Defect), CHB (Complete Heart Block)

Date of submission: 2024-04-14, *Date of acceptance:* 2024-07-13

Introduction

Ventricular septal defect (VSD) is a common congenital cardiac defect characterized by an abnormal connection between the ventricles. This results in the formation of a shunt, compromising the normal separation of oxygenated and deoxygenated blood and affecting overall cardiac function. VSD is the most prevalent congenital cardiac defect and can present in any part of the interventricular septum. The most common morphological variants are perimembranous VSD (pmVSD) and muscular VSD (mVSD), with location variants including anterior, mid, posterior, inlet, or outlet. The supracristal type is less common. Diagnosis can involve various abnormalities, ranging from isolated defects to those associated with other congenital malformations,

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arterial hypertension, and ventricular overload[1, 2]. Hemodynamic compromise may occur depending on the size and flow of the VSD, and closure is mandatory in hemodynamically unstable patients[3]. Traditionally, surgical methods have been the preferred approach for treating large defects[4]. However, these procedures have drawbacks that have encouraged the development of less invasive techniques, such as transcatheter closure using VSD occluder devices. Transcatheter closure of perimembranous VSDs has demonstrated fewer complications, shorter hospital stays, and avoidance of the need for cardiopulmonary bypass[5].

It is important to note that the use of VSD occluder devices, specifically the Amplatzer devices, has been associated with the occurrence of complete heart block (CHB) due to their potential impingement on the atrioventricular bundle (AV)[6]. Despite this complication, these devices have been introduced as a safer technique with lower complication rates compared to surgical methods. Interestingly, using Amplatzer duct occluders (ADO) (originally for patent ductus arteriosus (PDA) occlusion) has not demonstrated as high a CHB rate. Among the various devices used for transcatheter closure, the ADO types I and II have gained attention for their potential in closing pmVSDs[4, 5]. ADO Type I is designed to accommodate large PDAs using a single device, while ADO Type II consists of two articulating discs and a multilayered mesh construction, allowing it to conform to most PDA classifications[6, 7].

A meta-analysis conducted in 2021 assessed the effectiveness and associated complications of the Amplatzer Duct Occluder II for VSD closure. The findings of this meta-analysis, combined with the existing literature, provide crucial evidence supporting the acceptability of transcatheter device closure as an alternative to conventional surgical closure for perimembranous VSDs. This helps clinicians select the intervention method with the fewest complications[8].

This systematic review aims to provide a comprehensive assessment of the safety and efficacy of ADO types I and II for closing pmVSDs. By analyzing a large cohort of patients and synthesizing data from relevant studies, this review seeks to offer valuable insights into the outcomes and complications associated with ADO closure. Ultimately, it aims to contribute to the optimization of patient care and the development of evidence-based guidelines for device selection in pmVSD closure procedures.

Methods

This systematic review precisely adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, ensuring a robust and transparent approach to the literature search, study selection, and data synthesis[9].

Search Strategy

A comprehensive search strategy was used across multiple electronic databases, including PubMed, Google scholar and Cochrane Library, to identify English-language articles published up to 2022. The search strategy incorporated relevant keywords and Medical Subject Headings (MeSH) terms, such as "Amplatzer Ductal Occluder," "perimembranous ventricular septal defect," and "transcatheter closure." Various combinations of these terms were utilized to capture relevant studies. The number of records identified through the database search, as well as the number of duplicates removed, was carefully documented.

Study Selection

Two independent reviewers precisely screened the titles and abstracts of identified articles to ascertain studies meeting the inclusion criteria. Full-text assessment was then performed for potentially eligible studies, with any discrepancies resolved through consensus or consultation with a third reviewer. A transparent flow diagram, in accordance with PRISMA 2020 guidelines, illustrated the study selection process.

Eligibility Criteria

We included observational studies that reported complications, success rates, and mortality rates of transcatheter congenital perimembranous ventricular septal defect (VSD) closure using Amplatzer Duct Occluder (ADO) type I or II in human subjects. These studies had to be published in English, with no age limitations. Case reports, letters, conference papers, review articles, and meta-analyses were excluded. We also excluded studies that did not provide comprehensive information on patients, Amplatzer devices, complication/success rates, or studies involving patients with acquired perimembranous VSD or perimembranous VSDs with other coexisting heart defects.

Study Selection and Data Extraction

In the advanced search, we identified 1,500 articles. After removing duplicates, 20 articles were excluded. Following the exclusion of 180 studies, including conference abstracts, case reports, meta-analyses, and non-human research, 1,300 articles remained for title and abstract screening. We used a predefined checklist to assess the eligibility of studies. Based on pre-specified eligibility criteria, 1,250 articles were further excluded. Subsequently, 50 full-text articles were assessed for eligibility, and 23 articles were excluded due to age and language limitations. Finally, 27 studies involving 1,691 participants were included in this review.

The data extracted from the qualified articles were transferred to the Mendeley Reference Library software. Two authors (N.S. and S.R.) independently conducted primary screening by checking the titles and abstracts of all articles. Full-text screening of the remaining articles was performed. Any disagreements were resolved with the guidance of the supervising author (Figure 1).

For each study, the following data were extracted: first author's name, year of publication, study design, number of patients with confirmed congenital perimembranous VSD, mean age, mean size of the defect, type and rate of complications, follow-up echocardiography and ECG findings, device used for perimembranous VSD closure, rate of failure (need for surgery), and rate of mortality through percutaneous closure (Table 1). The primary outcome of interest was the comparison of complications and success rates between the two groups (ADO I and ADO II patients). The secondary outcomes included the assessment of complications and mortality rates for each group.

Quality Assessment

The methodological quality of the included studies was evaluated using appropriate tools, such as the Newcastle-Ottawa Scale for cohort studies to assess the risk of bias and ensure the reliability of the evidence[7]. This rigorous methodology aimed to provide a comprehensive and evidence-based evaluation of the safety and efficacy of Amplatzer Ductal Occluder types I and II in the context of perimembranous ventricular septal defect closure, in adherence to the PRISMA 2020 guidelines. The quality assessment results are depicted in Figure 2, reflecting the scores assigned to each study according to the NOS criteria.

Results

This systematic review analyzed the safety and effectiveness of Amplatzer Ductal Occluder (ADO) types I and II for closing perimembranous ventricular septal defects (pmVSDs). It reviewed 27 studies published between 2017 and 2022, providing insights into the safety and efficacy of ADO types I and II in pmVSD closure. The review included 1,691 participants, with 884 receiving ADO type I, 807 receiving ADO type II, and the ADO type for 39 participants remaining unknown. The average patient age was 6.1 years, and the mean VSD size was 5.4 mm. The median follow-up duration was 12 months, with predominantly retrospective studies (three prospective) comprising the dataset.

Examining the complication rates in detail, device embolism occurred in 2.29% (95% CI: 1.45–3.13) of cases, arrhythmia in 3.78% (95% CI: 2.64–4.92), complete heart block in 2.98% (95% CI: 2.05–3.91), and residual shunt in 28.45% (95% CI: 26.78–30.12). Further subgroup analysis revealed slightly varied outcomes for ADO types I and II. ADO type I demonstrated a commendable success rate, with a complete heart block incidence of 1.2% (95% CI: 0.75–1.65) and other complications maintained at 1.5% (95% CI: 1.02–1.98). Conversely, ADO type II was associated with a higher incidence of severe complications, particularly complete heart block at 4.5% (95% CI: 3.2–5.8).

The overall estimated success rate for device implantation was 97.3% (95% CI: 96.5–98.1), with only one procedure-related death reported. Complete heart block occurred in 2.3% (95% CI: 1.5–3.1) of cases, necessitating pacemaker implantation exclusively in ADO type II recipients. Residual shunts, the most frequent complication, were observed in 4.8% (95% CI: 3.9–5.7) of cases. In instances of closure failure, secondary surgical intervention was required in 7.51% (95% CI: 6.2–8.82) of cases.

In conclusion, ADO types I and II emerge as safe and effective options for pmVSD closure in both pediatric and adult populations. The results of this systematic review provide a foundation for informed clinical decision-making. However, the higher complication rates associated with ADO type II necessitate cautious consideration in selecting the appropriate device.

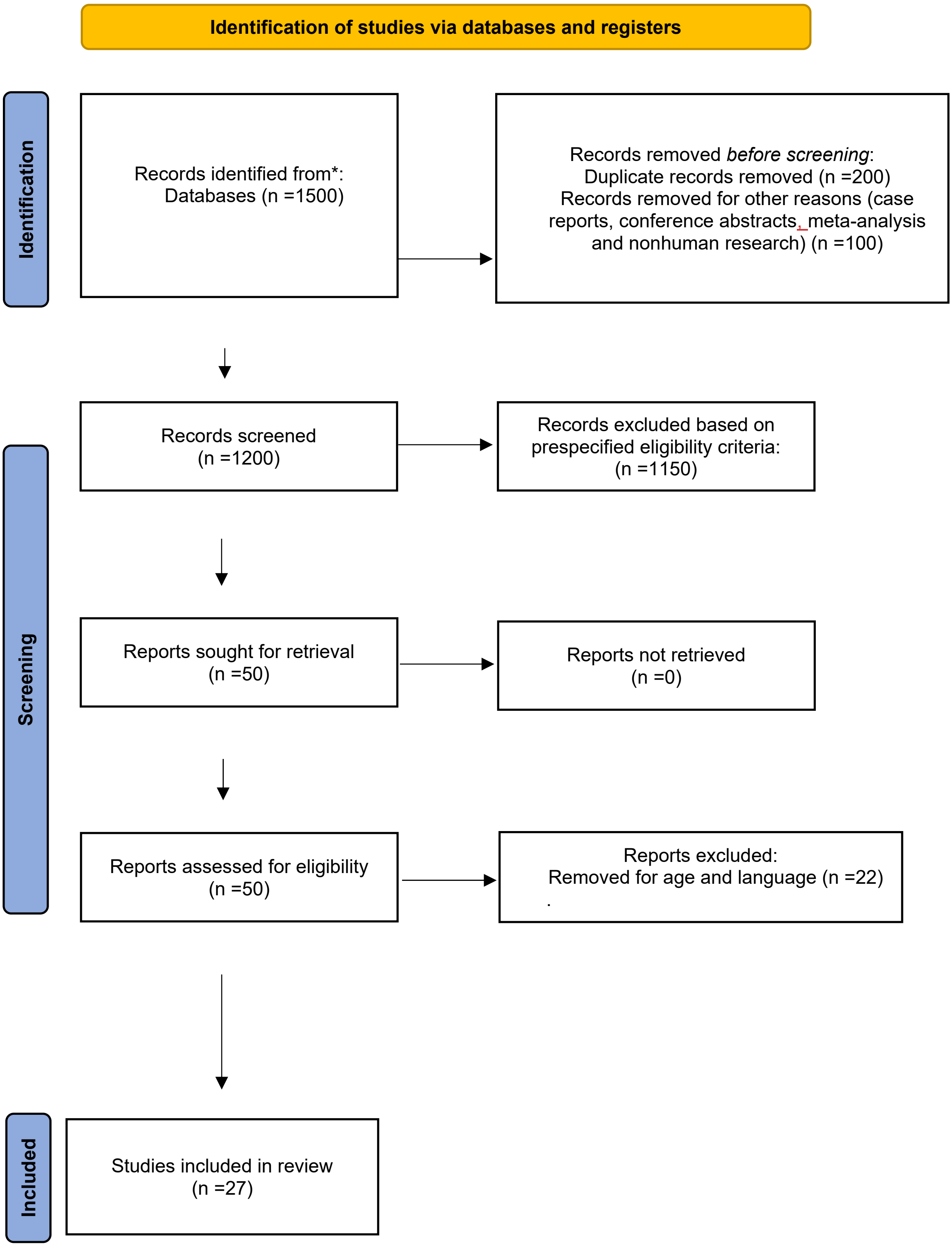

Figure 1. PRISMA 2020 flow diagram.

Table 1. Amplatzer Duct Occluder complications Complications

Authors	Device	Population	mean age (year)	Death	Mean (median) VSD size (mm)	Complications Device embolism	Arrhythmia	Residual shunt	Complete Heart block	Median Follow up (month)	Failure with ADO	Study type
El-Sisi, A. 2017 [8]	ADO I ADOII	13 17	4	0	5.6	0	0	2	0	12	1	Retrospective
Pamukcu,O. 2017 [9]	ADO II	49	7.2±4.3	0	3.7±1.4	0	0	3	1	66	0	Retrospective
Vijayalakshmi, IB1 2017 [10]	ADO II	61	9	0	4.5±0.7	0	3	0	1	10.8±5.4	0	Retrospective
Knop, M. T. 2018 [11]	ADO II	6	2.5	0	3	0	1	0	0	10.5	0	Retrospective
Nguyen, Hieu Lan 2018 [12]	ADO I	315	15.1±12.6	0	4.7±2	3	1	2	2	61.4±24.1	14	Retrospective
Zhao, L. J. 2018 [13]	ADO II	51	5.0±3.7	0	2.8±0.6	0	7	8	0	26.2	0	Retrospective
Narin, Nazmi 2018 [14]	ADO II	9	0.58	0	4	0	0	2	1	8.5	0	Retrospective
Esmaeili, A.2019 [15]	ADO II	15	5.1	0	4	0	0	4	0	66	0	Retrospective
Bosman M 2019 [16]	ADO I/ADO II	21 5	6.5	0	-	2(ado1)	0	8(6 ado1)	0	27	1(ado1)	Retrospective
Haddad, 2019 [17]	ADOI/ADO II	8 27	7.4±6.9	0	-	1	0	2	1	6.4	0	Retrospective
Pillai, Ajith Ananthakrishna 2019 [18]	ADO I	6	1.5	0	5.98	1	0	0	0	20	1	Retrospective
Shrestha, Manish 2019 [19]	ADO ADO II	22 20	7.1	0	6	0	0	0	1	6	1	Retrospective longitudinal cohort
Udink Ten Cate, F.E.A. 2019 [20]	ADO I	222	7	0	6.8 ± 2.2	0	5	0	3	6	0	Retrospective
Sobhy, R 2020 [21]	ADO I ADOII	55 51	5	0	4.8	1	0	3	1	36±25.7	1	Retrospective

Continued Table 1. Amplatzer Duct Occluder complications Complications

Authors	Device	Population	mean age (year)	Death	Mean (median) VSD size (mm)	Device embolism	Arrhythmia	Residual shunt	Complete Heart block	Median Follow up (month)	Failure with ADO	Study type
					Complications							
Al Senaidi, K. S. 2020 [22]	ADO I ADO II	39 26	3.54	0	5.7 ± 2.1	2(ado1)	-	2(ado2)	0	19	3(ado1)	Retrospective
Fatema, N N 2020 [23]	ADO II	79	5.94±4.67	0	5.5±1.8	0	0	0	0	28	0	Retrospective
Mijangos-Vázquez, R. 2020 [21]	ADO II	106	5	0	4.8	1	0	3	0	36±25.7	1	Retrospective
Ghosh,i 2020 [24]	ADO I	35	02.08±0.67	0	-	0	0	9	1	8.7	2	Retrospective
Jiang, D. 2021 [25]	ADO II	103	4.03±1.84	0	2.58±0.63	0	0	2	1	36	1	Retrospective
Ghaderian M 2021 [26]	ADO I	29	8.37±5.8	0	5.63±1.8	0	3	0	1	39.6±20.4	1	Retrospective
weewong, K 2021 Wongwaita [27]	ADO II	49	7.8	0	5.3 ± 1.8	0	0	3	0	12	0	Retrospective
Bergmann 2021 [28]	ADO I ADOII	3 33	6.2	1	-	-	2	2	0	74.4	0	cohort
Chen, 2021 [29]	ADO II AD0I	2 2	2	0	5.6	-	-	1	0	1	0	Retrospective
Liu, S. 2021 [30]	ADO II	28	3.6	0	< 5 mm	0	4	6	0	1	0	Retrospective
Jiang, Diandong 2021 [25]	ADO II	63	3.1	0	3.8	0	0	1	0	46	0	Retrospective
Mahua Roy 2022 [31]	ADO I ADO II	1 3	2	0	4.5	0	0	0	0	6	0	Retrospective
Xiaofei Z 2022 [32]	ADO II	4	7.25	0	3.00±1.05	-	0	0	0	4.4	0	Retrospective
Emad Jabour 2022 [33]	ADO I	113	10.6±7.31	0	5.69±1.63	0	0	6	2	12	5	prospective

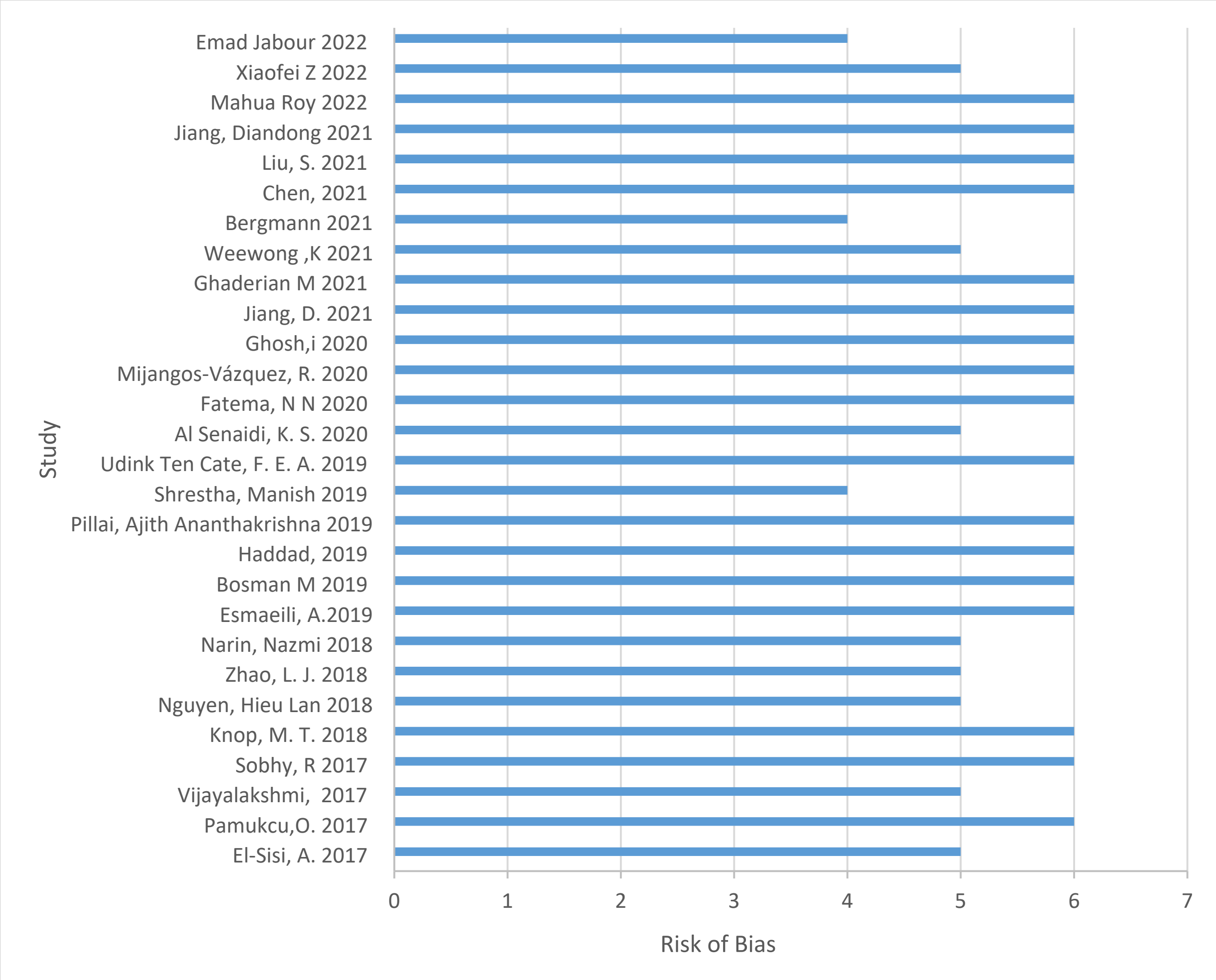

Figure 2. The image illustrates a summary of the Newcastle Ottawa Scale (NOS) risk of bias and regarding each risk of bias item for the included studies.

Discussion

This systematic review explores the safety and efficacy of ADO types I and II in pmVSD closure, building upon existing evidence that transcatheter closure using Amplatzer devices offers a lower complication rate compared to surgical repair for pmVSDs. Although perimembranous VSD is the most common congenital heart defect, transcatheter closure using Amplatzer devices has a lower complication rate than surgical repair. Congenital heart block (CHB) is one of the most critical complications due to the close proximity of the pmVSD margins to the His bundle, emphasizing the importance of appropriate size and type selection for Amplatzer devices[8].

We attempted to comprehensively analyze the success and complications of CHB with ADO in transcatheter closure of PMVSD in 27 studies involving 1691 patients with primary PMVSD who underwent transcatheter closure using either ADO I or ADO II. Arrhythmias, device embolism, surgical intervention, residual shunts, death, and most importantly, CHB are among the most common and life-threatening complications associated with transcatheter pmVSD closure using ADO I and ADO II. The off-label use of ADO for hemodynamically significant VSD closure has been reported to be an effective technique with a lower complication rate than other Amplatzer devices[11]. Device embolization and arrhythmias were more frequently associated with ADO type I. On the other hand, complete heart block was more commonly observed in ADO type II, leading to pacemaker implantation in some cases.

These differences could be attributed to variations in device design, deployment technique, or patient factors.

Secondary surgical intervention is necessary in cases of failure. There have been reports of ADO I failure with device embolization after the procedure, which could not be successfully resolved[2]. Ghaderian et al. reported a case in which transcatheter closure of a pmVSD was deemed unsuitable during angiography, resulting in massive intraventricular hemorrhage and subsequent brain death[12]. Gosh et al. described another cause of failure involving a pmVSD with subaortic extension, leading to significant aortic regurgitation due to valve impingement[13]. Kwelker et al. reported a case in which a VSD with two outlets closed by one ADO II resulted in CHB[14]. Additionally, Kwelker et al. reported a case of pmVSD closure using ADO I, in which the patient experienced dyspnea and easy fatiguability six weeks later. Surgical removal of the Amplatzer device and valve repair were successfully performed without complications[15, 16]. Another case involved a 10-year-old patient with mild tricuspid regurgitation and pmVSD who underwent transcatheter closure without complications. However, during the follow-up visits, the patient developed tears and entrapment of the anterior and septal leaflets, resulting in progression of tricuspid regurgitation and right heart enlargement. The device was removed and safely repaired[16]. CHB is one of the most serious complications of transcatheter closure of PMVSD. Ghosh et al. described two cases of post-procedure CHB, with the first case of complete atrioventricular block (CAVB).

Despite the favorable outcomes reported in this review, it is important to acknowledge the limitations of the study. The retrospective nature of many included studies introduces the potential for bias. Additionally, the heterogeneity of methodologies and patient populations makes it difficult to draw definitive conclusions about the safety and efficacy of ADO closure. Finally, the focus on short-term outcomes limits the assessment of long-term durability and late complications associated with ADO closure.

Imperative future research over the next five years should focus on refining patient selection criteria, evaluating long-term outcomes, and addressing the specific indications for each ADO type in the context of perimembranous ventricular septal defect closure.

Conclusions

This systematic review contributes valuable insights into the safety and efficacy of ADO types I and II for perimembranous ventricular septal defect closure. The results highlight the need for healthcare professionals to be aware of the differing complication profiles of each ADO type and to carefully monitor patients post-closure. The overall success rates are promising, but the higher complication rates observed with ADO type II, particularly in terms of complete heart block, warrant careful consideration in clinical decision-making.

The study also highlights the necessity for further research to delineate specific indications for using each type of Amplatzer device in the relevant population. Future investigations over the next five years should focus on evaluating long-term outcomes and the durability of ADO closure to provide comprehensive guidance for clinicians in selecting the most appropriate device for pmVSD closure.

Conflict of interests

The authors declare no conflict of interest.

Funding

There is no funding in this study.

Author's Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by SR, MG and NS.

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How to cite this article: Ghaderian M, Ramezani S, Behdad S, Gharipour M, Dianatkhah M, Hovesepian S, Salemi N. **Safety and efficacy of using amplatzer ductal occluder type I and II for peri membranous ventricular septal defect closure: A systematic review.** ARYA Atheroscler. 2024; 20(6): 54-64.

Appendix A.

Search strategy used for systematic literature review on Safety and efficacy of using Amplatzer™ Ductal Occluder type I and II for Peri membranous Ventricular Septal Defect closure with mesh. A computerized search was performed within three databases (PubMed, Scopus, and Cochrane).

PubMed publisher
(((“VSD closure “[Mesh]) OR (“vsd”[All Fields] AND (“closure”[All Fields] OR “closure s”[All Fields] OR “closures”[All Fields]) AND (“vsd”[All Fields] AND (“closure”[All Fields] OR “closure s”[All Fields] OR “closures”[All Fields])) AND ((“amplatzer”[All Fields] OR “amplatzer”[All Fields]) AND “duct”[All Fields] AND (“occlud”[All Fields] OR “occlude”[All Fields] OR “occluded”[All Fields] OR “occluder”[All Fields] OR “occluders”[All Fields] OR “occludes”[All Fields] OR “occluding”[All Fields])))

Scopus
((TITLE-ABS-KEY (“vsd occluder transcatheter closure “) OR TITLE-ABS-KEY (“amplatzer membranous vsd occluder transcatheter closure “) OR TITLE-ABS-KEY (“perimembranous ventricular septal defects transcatheter closure “) OR TITLE-ABS-KEY (“perimembranous ventricular septal defect device closure “) OR TITLE-ABS-KEY (“perimembranous ventricular septal defects catheter closure “)

Cochrane
((mesh* OR 4DDOME OR AIGISRx OR AlloDerm OR AlloMax OR ‘Bard Composix EX’ OR ‘BIO-A Tissue Reinforcement prosthesis’ OR CollaMend OR DermaMatrix OR DualMesh OR ‘Evolution P3EM’ OR FasLata OR FlexHD OR FortaGen OR ‘IntePro Lite’ OR InteXen OR NEOVEIL OR ‘Parietex composite’ OR Pelvicol OR Pelvisoft OR Pelvitex OR PerFix OR ‘Peri-Strips Dry’ OR PeriGuard OR Permacol OR Physiomesh OR SeamGuard OR Strattice OR Surgisis OR ‘TiLoop Bra’ OR Timesh OR Tutomesh OR Tutopatch OR Ultrapro OR Ventralex OR Veritas OR Vivosorb OR Vypro OR X-Repair OR XenMatrix):ab, ti) AND ((prevent* OR protect* OR prophyla*):ab, ti) AND ((((incision* OR cicatri* OR scar* OR ventral*) NEAR/3 (herni*)) OR ((abdominal* OR transabdominal*) NEAR/3 (surger* OR clos* OR defect* OR wall*)) OR laparotom* OR (midline NEAR/3 incision*)):ab, ti)

Amplatzer Septal Occluder Device; Gore-Helex Septal Occluder; Gore Helex Septal Occluder; Septal Occluder Devices; Device, Septal Occluder; Devices, Septal Occluder; Septal Occluder, Amplatzer; Occluder Devices, Amplatzer; Device, Amplatzer Occluder; Amplatzer Occluder Device; Occluder Device, Amplatzer; Devices, Amplatzer Occluder; Septal Occluders, Amplatzer; Amplatzer Occluder Devices; Amplatzer Septal Occluder; Amplatzer Septal Occluders; Helex Septal Occluder; Helex Septal Occluders; Septal Occluders, Helex; Septal Occluder, Helex; GoreHelex Septal Occluder; Septal Occluders, CardioSeal; Septal Occluder, CardioSeal; CardioSeal Septal Occluders; CardioSeal Septal Occluder; Occluder, Septal; Occluders, Septal; Septal Occluder; Septal Occluders; Amplatzer Occluders; Occluders, Amplatzer; Occluder, Amplatzer; Amplatzer Occluder; CardioSeal Occluders; CardioSeal Occluder; Occluder, CardioSeal; Occluders, CardioSeal

Synonyms: Device, Catheterization Closure; Devices, Catheterization Closure; Catheterization Closure Device; Catheterization Closure Devices; Closure Device, Catheterization; Closure Devices, Catheterization; Device, Vascular Closure; Closure Devices, Vascular; Devices, Vascular Closure; Vascular Closure Device; Closure Device, Vascular; Patches, Vascular Closure; Vascular Closure Patches; Closure Patches, Vascula