Original Research

Transcatheter Closure of Postinfarct VSD With the Amplatzer PIVSD Occluder: Results of a US Study

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ABSTRACT

Background: A postinfarct ventricular septal defect (PIVSD) is associated with high mortality and morbidity, particularly in patients with hemodynamic instability who are not suitable candidates for surgical repair. The Amplatzer PIVSD Occluder (Abbott) is indicated for transcatheter PIVSD closure in patients who are not satisfactory candidates for surgical repair. The objective of this study was to evaluate associated clinical outcomes.

Methods: A total of 131 patients underwent transcatheter PIVSD closure using the Amplatzer PIVSD Occluder between 2011 and 2021 as part of a post-approval, multicenter, retrospective, observational study. The patients were analyzed in 2 cohorts. Cohort 1 included 99 patients (age 68.6 ± 11.9 years) implanted from 2011 to 2016 and evaluated technical success, procedure survival, and 6-month survival. Cohort 2 included 32 patients (age 66.4 ± 10.9 years) implanted from 2012 to 2021 with postprocedure echocardiograms and evaluated 24-hour closure, 6-month closure, and 6-month survival.

Results: Technical success was achieved in 76.8% (76/99), procedure survival in 84.3% (75/89), and 6-month survival was observed in 37.2% of cohort 1 patients. Twenty-four-hour closure and 6-month closure were achieved in 53.1% (17/32) and 66.7% (4/6) of cohort 2 patients, respectively. Six-month survival was 46.4% of cohort 2 patients. Of the 16 deaths in cohort 2, 11 were cardiac-related, 4 were noncardiac-related, and 1 was of unknown etiology.

Conclusions: This study demonstrates high morbidity of patients undergoing PIVSD closure using the Amplatzer PIVSD Occluder and that the device continues to be a safe alternative to medical therapy in patients who are not satisfactory candidates for surgical repair of a PIVSD.

Introduction

A postinfarct ventricular septal defect (PIVSD) is one of the rare life-threatening mechanical complications occurring in <1% of patients following an acute myocardial infarction (AMI) which results in significant morbidity and mortality.[1–4] With the increased awareness of signs, symptoms, and early treatment of percutaneous coronary intervention for AMI, there has been a decline in the incidence of PIVSD in recent years.[5–7] However, during the COVID-19 pandemic, there were multiple reports of PIVSD as a result of a delay in patients seeking medical care for an AMI.[8,9] Those at risk of a PIVSD tend to be of an advanced age, female, hypertensive, with an absence of previous MI, not a current smoker, have an anterior AMI, and have a late presentation after an AMI.[1,2,10,11] When left untreated, PIVSD can result in rapid clinical deterioration characterized by cardiogenic shock, end-organ dysfunction, and mortality. Standard practices and procedures used for the treatment of a PIVSD include medical management, surgical repair, and percutaneous closure, including bridging with mechanical circulatory support to treatment. Medical therapy may transiently increase cardiac output and improve hemodynamics; however, the mortality rate of medical therapy alone exceeds 90%.[2] Surgical repair demonstrates better survival than medical therapy; however, mortality rates range between 19% and 54% and have been seen to be as high as 65%.[1,2,5,10,12] Although open cardiac surgery may be used to repair a PIVSD, many patients, particularly those in cardiogenic shock and with end-organ injury, may be poor candidates for surgery. Furthermore, patients who have significant residual shunting after open cardiac surgical repair may be at high risk for reoperation. Given the small size of this patient population, the Amplatzer PIVSD Occluder (Abbott) was submitted under the FDA's Humanitarian Use Exemption regulatory

pathway and gained approval in 2017. The Amplatzer PIVSD Occluder is the only FDA-approved, minimally invasive percutaneous alternative to achieving PIVSD closure in patients who are deemed not satisfactory candidates for surgical closure based on anatomical and/or overall medical condition per the physician and can serve as a bridge to future surgical repair if needed. As a condition of approval from the FDA, a postapproval study was required to collect data on this vulnerable patient population in whom an implant attempt with the Amplatzer PIVSD Occluder occurred. Herein, we present the results of this study.

Methods

The Amplatzer Postinfarct Muscular VSD Occluder Humanitarian Device Exemption Post-Approval Study (PIVSD PAS, ClinicalTrials.gov identifier: NCT03165526) was designed to evaluate the safety and probable benefit of the Amplatzer PIVSD Occluder (PIVSD Occluder) in transcatheter closure of muscular ventricular septal defects following a myocardial infarction. The PIVSD PAS was a multicenter, retrospective, observational study designed to assess technical success, acute and chronic closure, and acute and chronic survival of patients after implantation. Two cohorts were included in this study. Cohort 1 included all available patients who had an attempted device implant with the PIVSD Occluder under Emergency and Compassionate Use at 64 clinical sites between 2011 and the end of 2016. Cohort 2 was required to enroll a minimum of 30 patients with an echocardiography assessment postprocedure to satisfy FDA postapproval requirements. Clinical sites for cohort 2 with at least 1 successful prior implant with the PIVSD Occluder were screened for inclusion in the study. Living and deceased patients with a previously successful PIVSD Occluder implant were enrolled in cohort 2 at 16 clinical sites between November 2017 and November 2021. Each study site received approval from the local institutional review board prior to any study conduct or patient enrollment.

Cohort 1 included patients with a fully executed informed consent form required prior to each Emergency and Compassionate PIVSD procedure. These previously executed informed consent forms contained language that allowed for retrospective data collection. Cohort 1 was analyzed for technical success, acute survival, and chronic survival. This population provided an unbiased estimate of chronic survival for the intended population.

Cohort 2 consisted of living and deceased patients over the age of 18 years who had previously been successfully implanted with the PIVSD Occluder. For living patients, the subject or subject's legally authorized representative provided informed consent. Informed consent was not required to be obtained for deceased patients. Additionally, the subject's postprocedure echocardiogram was required to be evaluable for residual shunt by an independent echocardiography core laboratory. Cohort 2 was analyzed for acute closure, chronic closure, and chronic survival. Because only successfully implanted patients were included, this population provided a biased estimate of chronic survival.

Due to the retrospective nature of this study, no follow-up visits nor adverse event reporting was required for either cohort 1 or cohort 2.

Description of the device and procedure

The PIVSD Occluder is a self-expanding, double-disc device made from nitinol wire mesh intended for percutaneous occlusion of PIVSD in patients who are not suitable surgical candidates. The discs are connected by a waist corresponding to the size of the PIVSD. To improve closure, the discs and waist are filled with 3 polyester patches which are sewn securely to the device with polyester thread. Radiopaque marker bands at each end of the device provide visualization under fluoroscopy. The device is available in 5 different waist diameters, which represent the device sizes: 16 mm, 18 mm, 20 mm, 22 mm, and 24 mm. The left and right disc diameters are identical and are 10 mm larger than the waist diameter. All 5 device sizes have a uniform waist length of 10 mm. Device waist size selection is 3 to 4 mm larger in diameter than the largest VSD diameter obtained either by angiography or transesophageal echocardiography at the end of diastole. The device may be implanted using either an anterograde or retrograde approach using a 9F or 10F delivery sheath. The implant procedure is performed using a transcatheter approach in a cardiac catheterization laboratory setting under fluoroscopy and echocardiographic guidance.

Statistical analysis

Continuous data are reported as mean and standard deviation unless otherwise specified. The range is also provided to present the minimum and maximum values. Categorical data are reported as count and percentage.

Technical success was defined as a successful implant with the PIVSD Occluder in the PIVSD. An implant attempt occurred when the delivery system entered the subject's vasculature.

Acute and chronic closure were defined as the absence of a residual shunt $\geq$3 mm and was assessed based on an echocardiogram obtained immediately after a successful deployment, up to 7 days postprocedure and at 183 days (6 months) or later, respectively. Herein, chronic closure will be presented as a 6-month closure. The denominator was the number of patients in the analysis population and the numerator was the number of patients who experienced closure as determined by the echocardiography core laboratory. The 95% CI was calculated by using the exact binomial method.

Acute and chronic survival was defined as survival for at least 24 hours and 183 days (6 months) from the time of first successful implant, respectively. Herein, chronic survival will be presented as 6-month survival. The probability of a subject who is alive for at least 24 hours and 183 days (6 months) was estimated using the Kaplan-Meier method. Patients whose survival status was unknown for at least 24 hours and 183 days (6 months) postprocedure were censored on the date at which survival status was known. The 95% CI for the rate of chronic survival was calculated using Greenwood's formula for the variance of the Kaplan-Meier estimator. Data were analyzed by using SAS Software, version 9.4 (SAS Institute).

Results

Cohort 1

Cohort 1 included 99 patients with a mean age of 68.6 ± 11.9 years and 53.5% of patients were male (Table 1). The majority of AMI locations were either anterior (39.9%) or posterior/inferior (47.5%). Over half (67.6%) of patients were in cardiogenic shock. An intraaortic balloon pump (IABP) was placed in 52.9% of patients, and mechanical circulatory and respiratory support were utilized in 20% and 35.7% of patients, respectively. Most patients received vasopressors (92.1%) and inotropes (78.6%). Percutaneous PIVSD closure was completed within 30 days of the AMI in the majority (67.7%) of patients. Closure beyond 30 days post-AMI occurred in 24.2% of patients. Timing of closure for 8.1% of patients was unknown. Reasons for delay in intervention were not available given these data were retrospectively collected from Emergency and Compassionate Use cases.

Technical success was achieved in 76.8% of cohort 1 and the rate of acute survival was 84.3% (Table 2). The probability of survival for at least

Table 1. Patient demographics.

Characteristic	Cohort 1 N = 99	Cohort 2 N = 32
Age at the time of procedure, y	68.6 ± 11.9 (99) (23, 89)	66.4 ± 10.9 (32) (42, 89)
Male sex	53/99 (53.5%)	17/32 (53.1%)
Weight, kg	–	81.48 ± 16.76 (32)
Height, cm	–	168.47 ± 9.30 (31)
Body mass index, kg/m^2	–	28.34 ± 5.62 (31)
Medical history		
Hypertension	–	21/32 (65.6%)
Diabetes	–	10/32 (31.3%)
Hyperlipidemia	–	19/29 (65.5%)
History of smoking	–	18/31 (58.1%)
Number of diseased coronary arteries		
0	–	1/32 (3.1%)
1	–	16/32 (50.0%)
2	–	6/32 (18.8%)
≥3	–	9/32 (28.1%)
Location of acute MI		
Anterior (LAD)	39/99 (39.4%)	14/31 (45.2%)
Posterior/inferior (RCA)	47/99 (47.5%)	16/31 (51.6%)
Lateral (circumflex)	2/99 (2.0%)	1/31 (3.2%)
Unknown	11/99 (11.1%)	–
Management of acute MI		
Thrombolytic therapy	–	9/26 (34.6%)
PTCA with stent	–	15/31 (48.4%)
PTCA without stent	–	1/31 (3.2%)
CABG	–	3/31 (9.7%)
Hemodynamic instability assessment		
Cardiogenic shock	50/74 (67.6%)	18/32 (56.3%)
IABP	45/85 (52.9%)	14/32 (43.8%)
MCS device[a]	18/90 (20.0%)	7/32 (21.9%)
Mechanical respiratory support	25/70 (35.7%)	13/32 (40.6%)
Vasopressors	35/38 (92.1%)	12/31 (38.7%)
Inotropes	11/14 (78.6%)	10/31 (32.3%)
ICU status		
Subject in ICU	–	21/32 (65.6%)
Subject not in ICU	–	11/32 (34.4%)
Location of primary VSD		
Anterior	–	2/32 (6.3%)
Posterior/inferior	–	6/32 (18.8%)
Apical	–	9/32 (28.1%)
Midseptum	–	15/32 (46.9%)
Time of procedure from MI		
<7 days	20/99 (20.2%)	8/32 (25.0%)
7-30 days	47/99 (47.5%)	9/32 (28.1%)
≥30 days	24/99 (24.2%)	11/32 (34.4%)
Unknown	8/99 (8.1%)	4/32 (12.5%)

Values are mean ± SD (n) (range), n/N (%), or mean ± SD (n).
CABG, coronary artery bypass grafting; IABP, intraaortic balloon pump; ICU, intensive care unit; LAD, left anterior descending coronary artery; MCS, mechanical circulatory support; MI, myocardial infarction; PTCA, percutaneous transluminal coronary angioplasty; RCA, right coronary artery; VSD, ventricular septal defect.
[a] Left ventricular assist device, extracorporeal membrane oxygenation; percutaneous pump.

Table 2. Primary effectiveness and safety end point results.

End points	Results	95% CI
Cohort 1		
Rate of technical success	76/99 (76.8%)	67.2–84.7
Rate of acute survival	75/89 (84.3%)	75.0–91.1
Cohort 2		
Rate of acute closure	17/32 (53.1%)	34.7–70.9
Rate of 6-month closure	4/6 (66.7%)	22.3–95.7

Values are n/N (%) unless otherwise noted.

6-months postprocedure was 37.2% (Central Illustration). A total of 43 (43.4%) deaths occurred within 30 days of the index procedure, and 4 (4%) occurred after 30 days and up to 6 months postprocedure.

Cohort 2

Cohort 2 included 32 patients (14 living and 18 deceased at the time of enrollment) with a mean age of 66.4 ± 10.9 years and 53.1% were male (Table 1). Among these patients, 5 patients presented during the COVID-19 pandemic. Over half of patients had a medical history of hypertension (65.6%), hyperlipidemia (65.6%), and smoking (58.1%). All but 1 patient had at least 1 diseased coronary artery. Of the patients with a reported AMI location, the majority were either posterior/inferior (51.6%) or anterior (45.2%). The location of the PIVSD was midseptum in 46.9%, apical in 28.1%, posterior in 18.8%, and anterior in 6.3% of patients. The majority of PIVSD (86.7%) were simple in morphology. Over half of patients were in the ICU (65.6%), in cardiogenic shock (56.3%) and had congestive heart failure (61.3%) at the time of PIVSD closure. Further patient-level baseline data can be found in the supplemental material (Supplemental Table S1).

The average procedure time for cohort 2 was 169.9 ± 81.5 minutes (Table 3). Transesophageal echocardiography was the most utilized imaging modality to assess the PIVSD (84.4%) with 84.4% of procedures also using angiography. All PIVSD Occluder sizes were used. One patient received two 16 mm PIVSD Occluders within a single defect, and 1 patient had a reintervention with an additional device implanted. Patient-level procedural data and outcomes can be found in the supplemental material (Supplemental Table S2).

Acute and 6-month closure success was achieved in 53.1% and 66.7% of patients, respectively (Table 2). Of the 32 enrolled patients, a total of 11 completed a 6-month follow-up visit (Table 4). Of the 11 completed visits, 6 echocardiograms met all the parameters for the 6-month closure end point and were included in the analysis. Of the remaining 5 patients completing a 6-month visit, 4 had a residual shunt status reported by the site. Of these site-reported residual shunts, 2 patients had a shunt graded as none/trivial and 2 patients had a small shunt.

Mortality occurred in half (50%) of patients. Thirteen occurred within 30 days postprocedure and the remaining 3 occurred after 30 days but within 6 months postprocedure. Of the 16 deaths, 11 were classified as cardiac, 4 as noncardiac, and 1 death was due to an unknown reason. Reasons for mortality included multisystem organ failure (5), cardiovascular events (5), residual PIVSD shunting leading to further decompensation (2), cancer (2), cerebrovascular accident (1), and unknown causes (1). All cardiac deaths occurred within 30 days postprocedure. The 3 deaths occurring after 30 days were due to cancer (2) and an unknown cause (1). The probability of survival for at least 6-months postprocedure for cohort 2 was 46.4% (Central Illustration).

Discussion

Patient characteristics and outcomes of this postapproval study are similar to those previously reported in literature.[2,11,13,14] Various risk factors for mortality have been published; however, a few common risk factors include advanced age and cardiogenic shock.[1,2,5,10–12,15,16] Most recently, Giblett et al[15] reported that cardiogenic shock and number of diseased coronary arteries were associated with long-term mortality. Interestingly, none of these risk factors were found to be statistically significant in cohort 2 of our study. However, it is understood that patients with these risk factors, especially those in cardiogenic shock, are more likely to be at an increased risk of mortality. When reviewing the 9 patients older than 72 years of age in cohort 2 (Supplemental Table S1), most (7/9) were in cardiogenic shock and all had at
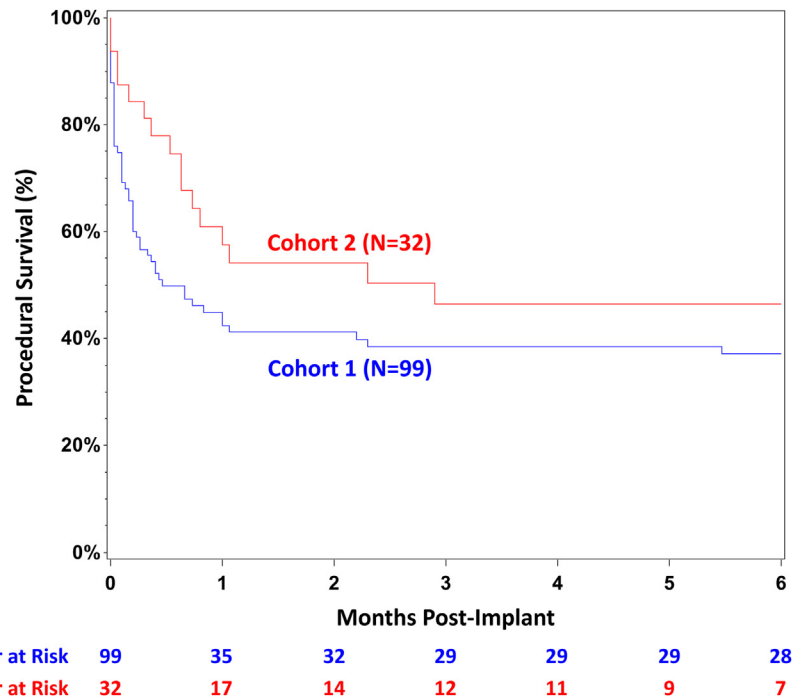
Central Illustration.

Probability of 6-month (183 days) survival for cohorts 1 and 2. Both cohort 1 and 2 were assessed using the Kaplan-Meier method. Probability of survival was 37.2% and 46.4% at 6 months postprocedure for cohorts 1 and 2, respectively. Cohort 1 included all available patients (N = 99) who underwent a PIVSD Occluder implant attempt under Emergency and Compassionate Use between 2011 and 2016. Cohort 2 patients (N = 32) were enrolled across 16 clinical sites between 2017 and 2021.

least 1 diseased coronary artery; however, among these 9 patients, only 4 fatalities occurred (Supplemental Table S2). Time from AMI to procedure ranged from 2 to 80 days, with all fatalities occurring in patients who were closed within 14 days of the AMI. Additionally, all mortalities occurred in patients with a large (≥ 3 mm) postprocedure residual shunt.

Although we did not find any significant statistical risk factors for mortality in PIVSD patients, we observed that patients with older age (>72 years), presence of cardiogenic shock, early closure of defect (within 14 days), and presence of a large postprocedure residual shunt

had higher mortality. This is not surprising given these are the highest-risk patients with a PIVSD.

There remains controversy over the appropriate timing from AMI to PIVSD closure. Current European Society of Cardiology and American College of Cardiology/American Heart Association guidelines recommend immediate surgical closure for those with mechanical defects, such as a PIVSD, following an AMI.[3,17] However, these guidelines contradict what is typically seen in practice. Many reports of delayed closure (surgical or percutaneous) suggest better outcomes due to septal tissue healing, improving the chances of successful closure.[1,5,10,11,18,19] However, timing of closure can be a double-edged sword: although delaying PIVSD closure increases the chances of tissue healing, thus improving the chances of definitive closure, a subset of patients have severe clinical deterioration and cannot wait unless managed with long-term mechanical circulatory and respiratory support. Early intervention could be associated with an increased risk of incomplete closure. Regardless of timing between AMI and PIVSD closure, the average procedure time seen in this study was nearly 3 hours, further emphasizing the complex nature of PIVSD closure. Techniques such as delivering the occluder via a retrograde arterial approach without needing to form an arterial-venous rail have been previously proposed as a way to streamline and shorten percutaneous PIVSD closure.[20]

In the 16 fatalities observed in cohort 2 (50%), 10 patients underwent PIVSD closure within 14 days of the AMI. However, of the 16 survivors, 4 had PIVSD closure within 14 days of the AMI; 2 patients even had large residual shunts. Thirteen of the 16 fatalities occurred within ≤ 30 days of PIVSD closure. For patients who survived the initial 30 days postprocedure (N = 16), 3 died between 32 days and 87 days postprocedure due to cancer (2) and an unknown (1) cause. The COVID-19 pandemic added an additional layer of complexity when determining timing of PIVSD closure. Five patients from cohort 2 presented during the pandemic (after March 15, 2020). All 5 were in cardiogenic shock and treated with mechanical respiratory support.

Table 3. Cohort 2 procedural characteristics.	
Variable	N = 32
Procedure time, min	169.9 ± 81.5 (29)
Echo assessment	
Intracardiac echocardiography	2/32 (6.3%)
Transesophageal echocardiography	27/32 (84.4%)
Transthoracic echocardiography	3/32 (9.4%)
Angiogram	27/32 (84.4%)
Device size #1 implanted	
16 mm	9/32 (28.1%)
18 mm	6/32 (18.8%)
20 mm	6/32 (18.8%)
22 mm	4/32 (12.5%)
24 mm	7/32 (21.9%)
Access site #1	
Right femoral	10/32 (31.3%)
Right transjugular	13/32 (40.6%)
Left atrial approach	9/32 (28.1%)
Device size #2 implanted	
16 mm	1/1 (100.0%)
Access site #2	
Right transjugular	1/1 (100.0%)

Values are mean ± SD (n) or n/N (%).

Table 4. Cohort 2, 6-month follow-up listing.

Patient	Location of VSD	VSD morphology	Days from MI to procedure	Device size, mm	Postprocedural residual shunt	Six-month residual shunt	Reviewer	Qp:Qs
2	Apical	Simple	N/A	24	≥3	≥1 and <3	Site	
3	Midseptum	Simple	N/A	16	≥1 and <3	<1	Site	
4	Midseptum	Simple	91	16	≥3	≥1 and <3	Core lab	
5	Posterior/inferior (RCA)	Complex	133	20	≥3	≥3	Core lab	3.3
7	Posterior/inferior (RCA)	Simple	80	20	<1	<1	Core lab	
8	Midseptum	Simple	111	16	≥1 and <3	<1	Site	
14	Apical	Simple	28	18	≥3	≥3	Core lab	4.98
19	Anterior (LAD)	Simple	592	16	<1	≥1 and <3	Core lab	
20	Midseptum	Simple	16	24	≥3	<1	Core lab	
21	Midseptum	Simple	42	20	<1	≥1 and <3	Site	

LAD, left anterior descending coronary artery; MI, myocardial infarction; N/A, not available; Qp:Qs, ratio of pulmonary flow to systemic flow; RCA, right coronary artery; VSD, ventricular septal defect.

Percutaneous PIVSD closure was completed within 8 days of the AMI diagnosis (range, 1-8 days). Three patients died: 2 on the day of the procedure and 1 two days following the implant. It was decided by the treating clinical team that it was in these patients' best interest to have PIVSD device closure as soon as possible rather than a deferred approach. Due to "shelter in place" instructions during the pandemic period, it is plausible these patients experienced AMI symptoms for days leading up to their eventual presentation to the hospital, causing further deterioration before receiving care. Nonetheless, these observations further emphasize the complicated nature of this patient population and the importance of individualized care. Treatment algorithms have been proposed for the management of AMI and PIVSD but vary across clinicians and institutions with no one agreed-upon regimen.[6,7,18,21] In some patients presenting with early AMI symptoms and who are not taken directly to the cardiac catheterization laboratory, thrombolytic therapy may be used. Approximately one-third of cohort 2 patients (34.6%, 9/26) received thrombolytic therapy. Of these 9 patients, 6 died. All 6 fatalities occurred within 30 days of the PIVSD procedure with 4 occurring within 7 days of the procedure. The time from AMI to PIVSD closure in these 4 patients ranged from 2 to 12 days. Given that early thrombolytic therapy in patients presenting with an AMI is thought to have the potential to prevent a PIVSD and thereby improve patient survival, the results of this study demonstrate that thrombolytic therapy may not always prevent a PIVSD and align with the findings of Deja et al.[12] However, the involvement of a multidisciplinary heart team is critical for optimal management of these patients. Although no one treatment algorithm exists, percutaneous PIVSD closure, with reports of implant success consistently >85%,[11,14,22] is an important consideration for management of PIVSD. This study reaffirms that percutaneous PIVSD closure can be completed with a high probability of acute success and plays an important role in the treatment of PIVSD following an AMI.

Limitations

The retrospective enrollment and small sample size are the primary limitations of this study. However, given the nature of this patient population, large, prospective studies are unrealistic. Additionally, cohort 2 allowed for enrollment of deceased subjects in which informed consent was not required. This can cause a proclivity to enroll deceased patients over those living. The nature of cohort 1 enrollment led to a more limited set of data which leaves some questions unanswered; however, the data presented is consistent with cohort 2 and the literature, allowing us to infer this patient population is representative of those affected with a PIVSD.

Conclusion

A well-defined treatment plan for PIVSD management is still unknown. However, percutaneous closure plays an important role in the treatment of these patients, especially those who are not suitable candidates for surgical repair. Many centers have reported improved results by delaying PIVSD intervention for at least 14 days following an AMI, but this approach incorporates survivorship bias. The results of this study are consistent with the literature and further emphasize the complexity of this patient population. Further investigation and studies are warranted for the management of PIVSD in order to increase the probability of survival and outcomes for these high-risk patients.

Declaration of competing interest

Vijay Iyer is a proctor for Edwards Lifesciences, Boston Scientific, and Medtronic, on the advisory board of Boston Scientific and Medtronic, and on the speaker's bureau for Abiomed. Courtney Weiler and Dan Gutfinger are full-time employees of Abbott. Puvi Seshiah is a proctor for Medtronic transcatheter mitral valve replacement. Jon Resar has received institutional research grants from Abbott, Medtronic, and Edwards Lifesciences. Vaikom Mahadevan is a principal investigator for Abbott clinical trials. William Merhi, Biswajit Kar, and J. Curtis Fudge report no disclosures.

Funding sources

Ethics statement and patient consent

This study adhered to all relevant ethical guidelines. Each study site received approval from the local institutional review board prior to any study conduct or patient enrollment, and patient consent was obtained when required.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2024.102016.

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