Healthy Blue

Medical Policy

Subject:	Transmyocardial/Perventricular Device Closure of Ventricular Septal Defects		
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Description/Scope

This document addresses the transmyocardial/perventricular device closure of ventricular septal defects (VSDs). Transmyocardial/perventricular device closure of a VSD approaches the defect by puncturing the wall of the right ventricle, rather than via a percutaneous approach. It has generally been performed as part of a combination "hybrid" procedure, which involves standard cardiac surgical techniques for correction of coexisting abnormalities, combined with a perventricular intervention for VSD closure. The technique has been investigated as an alternative to percutaneous transcatheter techniques combined with cardiac surgery, and it is for the repair of complex congenital cardiac defects that are not readily amenable to more established approaches.

Note: This document does not address the percutaneous transcatheter closure of ventricular septal defects.

Position Statement

Investigational and Not Medically Necessary:

Transmyocardial/perventricular device closure of ventricular septal defects is considered **investigational and not medically necessary.**

Rationale

Transmyocardial/perventricular device closure of VSDs involves deployment of an occlusive device via a right ventricular puncture and is being investigated as an alternative to a percutaneous transcatheter approach, particularly in infants or other individuals with poor vascular access. It has generally been reported, when performed in combination with cardiac surgery for coexisting abnormalities in a so-called "hybrid" procedure, as involving standard cardiac surgery performed in tandem with interventional transcatheter techniques for closure of a coexisting defect. It is reported that the perventricular approach may be performed, in some cases, without the need for cardiopulmonary bypass. Currently, these procedures are performed using an occluder device, such as the AMPLATZER® Muscular VSD occluder (AGA Medical Corporation, Golden Valley, MN), which is not FDA approved for this purpose.

Several small studies, mostly from single centers and with a small number of subjects, have reported on the transmyocardial/perventricular approach (Bacha, 2003, 2005; Bendaly, 2011; Holzer, 2004; Kang, 2015; Molaei, 2017; Patel, 2005; Zhu, 2013). Although promising, these reports were limited by a retrospective design, short follow-up period, or lack of randomization.

In a multicenter, retrospective cohort study, Gray and colleagues (2017) evaluated acute and midterm outcomes of hybrid perventricular VSD closure performed with the Amplatzer occluder device. The researchers categorized 47 subjects into 2 groups: subjects who had a simple perventricular closure and subjects who had a complex perventricular closure that was combined with another cardiac surgical procedure. The median age was 5.2 months. The hybrid perventricular procedure was successful in 100% of the simple group (n=22) and in 84% of the complex group (n=21/25). Overall, serious adverse events (SAE) occurred in 9/47 subjects (19%). In the simple group, there were 2/22 (9%) SAEs, including a malpositioned VSD device 4 days postop and a left pseudoaneurysm 14 months postop. In the complex group, there were 7/25 (28%) SAEs, including perforation by the delivery sheath, AV valve insufficiency resulting in transplantation, and 4 deaths. Of the 39 subjects available at a median follow-up of 19.2 months, 90% (35/39) were free from cardiac symptoms and had normal biventricular systolic function. Limitations of the study included the retrospective design, small sample size, variability in the complexity of the VSDs, and short follow-up. The authors stated that "longer-term studies are necessary to evaluate for any late device-related adverse outcomes."

Voitov and colleagues (2017) performed a prospective randomized trial to compare the perventricular device closure (PVDC) approach to conventional surgery for VSD closure. A total of 640 subjects were randomized to either have PVDC surgery with a Lepu occluder (Lepu Medical Technology Co., Ltd., Beijing, China) (n=320) or conventional surgery (n=320). The subjects, who were an average of 36.2 months old, were examined at 3, 6, 12 and 24 months post-procedure. The success rate in the PVDC group was 96.6%; however, 11 PVDC procedures (3.4%) had to be converted to conventional surgery: 1 procedure (0.3%) due to a complete AV block that was resolved after conversion, 6 procedures (1.9%) due to a > 3 mm residual shunt, and 4 procedures (1.3%) due to the occluder size not matching the VSD diameter. During surgery, blood loss was 27.6 ml in the PVDC group and 38 ml in the conventional group (p=0.015). Intraoperative blood transfusions were given to 285 subjects (86.1%) in the conventional group due to cardiopulmonary bypass priming, but none were needed in the PVDC group (p<0.001). Postoperatively, 3 subjects (1.0%) in the PVDC group underwent a pericardiocentesis for pericardial effusion compared to 1 subject (0.3%) in the conventional group (p=0.284). At discharge, 34 subjects in the conventional group (10.3%) and 17 subjects (5.5%) in the PVDC group had a trivial residual shunt (< 2 mm) (p=0.026). Pulmonary artery pressure was reduced from 35.9 mmHg to 23.9 mmHg in the PVDC group and from 36.1 mmHg to 24.4 mmHg in the conventional group, but the difference between the groups was not statistically significant (p=0.418). At 24 months post-procedure there were no deaths. The conventional group had more residual shunts, but the researchers noted that the reason could be from the technique used. The authors concluded that, compared to conventional surgery, the PVDC approach is "less traumatic, reduces the operation time and ICU and hospital stays, and provides excellent cosmetic results." Limitations of the study included a short follow-up duration, loss to follow-up, and data from only a single center.

In a single-center retrospective study, Fang and colleagues (2018) compared PVDC with transcatheter device closure and median sternotomy for perimembranous VSD. The researchers reviewed 247 medical records and divided the subjects into the following groups: median sternotomy group (n=86), perventricular group (n=90), and transcatheter group (n=71). Exclusion criteria included age below 6 months, weight below 10 kg, respiratory diseases, history of thorax procedure, severe valvular regurgitation, and right-to-left shunt caused by pulmonary hypertension. A successful VSD closure was defined as no large residual shunt (< 2 mm) as confirmed by

transthoracic echocardiography (TTE). VSD occluder devices used included the Amplatzer VSD occluder and a China-made occluder (Shan Dong Visee Medical Apparatus Co. Ltd of China). Follow-up assessments were made at 3 and 12 months after the VSD closure and included clinical examination, ECG, chest x-rays, and TTE. VSD repair was attempted and successful in 86/86 in the median sternotomy group, 87/90 in the perventricular group, and 67/71 in the transcatheter group. The failures were successfully converted to surgical repair and were not counted in the median sternotomy group. Between the groups, the researchers found a similar success rate. In addition, there were no significant differences in SAEs. The median sternotomy group had the longest mechanical ventilation time, operative time, hospitalization time, time in intensive care, and volume of blood transfusion (p=0.05). SAEs seen in the perventricular group and transcatheter group included complete atrioventricular heart block (1 subject each group), new mild aortic valve regurgitation (1 subject each group), and moderate-severe aortic valve regurgitation (1 subject in perventricular group and 2 subjects in transcatheter group). The researchers concluded that device closure may be an alternative to conventional surgical repair, and perventricular closure was preferred due to TTE guidance, shorter learning curve, and no x-ray exposure. Limitations of the study included the retrospective nonrandomized design, single-center location, and short follow-up duration. The researchers recommended future multicenter studies.

Liu and colleagues (2018) conducted a prospective, randomized, open-label, non-inferiority trial to compare PVDC to open surgery for repairing VSDs in infants and children. The researchers randomized 200 subjects with VSD to receive treatment with PVDC (n=100) or treatment with open surgery (n=100). Inclusion criteria included operation-naïve infants and children aged 5-60 months with echocardiography-confirmed isolated perimembranous VSD (diameter of 3-10 mm). Exclusion criteria included significant right-to-left or bidirectional shunting, presence of aortic prolapse, more than moderate aortic regurgitation, more than moderate pulmonary hypertension despite medical therapy, presence of infective endocarditis, history of pericardiotomy and transcatheter closure, or high-risk for perventricular or surgical closure. The primary outcome was efficacy, safety, and cardiorespiratory compromise. Efficacy was defined as echocardiography-determined complete closure at discharge, safety was defined by minor and major adverse events, and cardiorespiratory compromise was defined as the development of compromised cardiorespiratory performance on the basis of a composite of cardiac electrophysiological adaption, hemodynamic dysfunction, myocardial viability impairment, septal mechanical deformation, respiratory mechanical alteration, ventilator and gas exchange insufficiency or oxygenation and tissue perfusion inadequacy. There were 2 procedure failures in the perventricular group (1 aortic regurgitation after deployment of the occluder and 1 atrioventricular block immediately after occluder release). Both subjects were converted to open surgery and analyzed in the as-treated (AT) population surgical group. In addition, 1 subject in the perventricular group developed postoperative complete atrioventricular block, was converted to open surgery, and was analyzed in the AT population surgical group. Complete closure at discharge was 94.9% in the perventricular group and 95.9% in the surgical group. The non-inferiority of perventricular to surgical closure regarding complete closure at discharge was not shown in the intention-to-treat population (ITT) (absolute difference −0.010; 95% confidence interval [CI], −0.078 to 0.058) and modified intention-to-treat (mITT) populations (−0.010; 95% CI, −0.069 to 0.048), but was shown in the per protocol (PP) (0.010 (95% CI, −0.043 to 0.062) and as-treated (AT) populations (0.048; 95% CI, −0.009 to 0.106). The researchers did not find any significant differences in the frequency of major or minor adverse events between the groups (p>0.05). Perventricular closure was found to significantly reduce postoperative cardiorespiratory compromise compared to surgical closure in the mITT population (p>0.05). The researchers concluded that PVDC has comparable safety to open surgery and reduces the rate of compromising

cardiorespiratory performance. However, the findings "should be interpreted in the context of populations of different patterns." The study is limited by the disparity of results according to populations of different patterns, and the authors note that "the true effect of perventricular closure versus surgical closure on efficacy cannot be entirely determined."

In a single-center study, Huang and colleagues (2019) compared PVDC and percutaneous surgery for isolated VSD. A total of 572 subjects were divided into two groups based on the treatment performed: PVDC (n=427) or percutaneous (n=145). PVDC was performed using an occluder device manufactured in China (Lifetech Scientific and Shan Dong Visee Medical). In the PVDC group, 15 subjects were converted to conventional surgery due to new moderate-severe aortic valve regurgitation (n=6), failure to establish a transfer orbit (n=1), occluder dislodgement (n=2), significant residual shunt (n=5), and immediate Mobitz type II atrioventricular block (AVB) (n=1). In the percutaneous group, 10 subjects were converted to conventional surgery due to new moderate-severe aortic valve regurgitation (n=5), occluder dislodgement (n=2), significant residual shunt (n=2), and immediate AVB (n=1). Successful VSD closure rates were not statistically different between the groups. The PVDC group had a longer stay in the ICU ($p<0.05$); however, overall hospital stay was similar between the groups. The percutaneous group had longer operative times ($p<0.05$). During follow-up, both groups had one case of late-onset complete AVB requiring pacemaker placement. The researchers concluded that both procedures have advantages and disadvantages, and longer follow-up is needed to evaluate outcomes. The study was limited by the retrospective, single-center design and lack of randomization.

In a 2019 meta-analysis, Hong and colleagues analyzed PVDC for perimembranous VSD. A total of 15 studies were included (8 case series and 7 case-control; n=1368). Median follow-up ranged from 2 months to 5 years. The overall pooled success rate was 0.95 (95% CI, 0.92 to 0.97). The most common minor complication was residual shunting (n=95/1368). A total of 80 subjects were converted to conventional surgery due to significant residual shunting (36.4%), mild to significant aortic regurgitation (35.2%), severe arrhythmia (11.4%), failure to establish a path (9.1%), and mild to significant tricuspid regurgitation (8.0%). The pooled rate of severe intraoperative complications was 0.050 (95% CI, 0.028 to 0.071; p=0.000). The researchers concluded that PVDC may be a safe and effective alternative to conventional surgery but recommended more detailed observations in larger studies. The meta-analysis was limited by the heterogeneity of the studies, lack of information reported, and lack of randomized controlled studies.

The published scientific evidence currently available is insufficient to demonstrate the long-term safety and efficacy of transmyocardial/perventricular approaches to closure of VSDs, as compared to conventional treatment options.

Background/Overview

VSDs may be congenital or an uncommon complication following a myocardial infarction. When there is a large opening between the ventricles, a large amount of oxygen-rich blood from the heart's left side is pumped through the defect into the right side and to the lungs, following the principle of blood flowing from a higher pressure to a lower pressure as the lung's blood pressure is normally much lower than the systemic pressure. This extra blood

pumping to the lungs creates inefficiency. Normally, half of the body's blood is flowing through the right side of the heart to the lungs, and half is flowing through the rest of the body. The extra blood flowing into the lungs (pulmonary circulation) can interfere with normal lung function. The extra blood in the circulatory system causes the heart to try to compensate by getting larger. It can do this to a point, but eventually this enlargement and extra work can lead to heart failure. Additionally, the lungs compensate for the added blood flow by increasing the resistance in the lung's blood vessels. Over time, these changes in the lungs' blood vessels cause permanent damage and lead to a condition known as pulmonary hypertension.

If the opening between the ventricles is small, it does not strain the heart. In that case, the only abnormal finding is a loud murmur. Closing small ventricular septal defects may not be needed, except perhaps to try to remove a possible site of infection known as endocarditis. These holes often close on their own during early childhood. However, if the opening is large, closing the hole in the first 2 years of life is recommended, even in individuals with few symptoms, to prevent serious problems later. Repairing a VSD restores the blood circulation to normal. The transmyocardial approach, otherwise known as perventricular, is a hybrid procedure being investigated as an alternative to the transcatheter procedure in individuals with complex congenital cardiac defects. To date, no devices have been granted final FDA approval for this application.

Definitions

Ventricular septal defect (VSD): An opening in the wall between the right and left ventricles.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

33999	Unlisted procedure, cardiac surgery [when specified as transmyocardial transcatheter closure of ventricular septal defect, with implant, including cardiopulmonary bypass if performed]

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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11. Huang XS, Luo ZR, Chen Q, et al. A comparative study of perventricular and percutaneous device closure treatments for isolated ventricular septal defect: a Chinese single-institution experience. Braz J Cardiovasc Surg. 2019; 34(3):344-351.
12. Kang SL, Tometzki A, Caputo M, et al. Longer-term outcome of perventricular device closure of muscular ventricular septal defects in children. Catheter Cardiovasc Interv. 2015; 85(6):998-1005.
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17. Zhu D, Tao K, An Q, et al. Perventricular device closure of residual muscular ventricular septal defects after repair of complex congenital heart defects in pediatric patients. Tex Heart Inst J. 2013; 40(5):534-540.

Websites for Additional Information

1. American Heart Association. Available at: http://www.heart.org. Accessed on November 11 , 2020.

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AMPLATZER Device
CardioSeal® Device
Perventricular Device Closure
Transmyocardial Device Closure
Ventricular Septal Defect
VSD

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References and Websites sections.
Reviewed	11/07/2019	MPTAC review. Rationale, References, and Websites sections updated.
Reviewed	01/24/2019	MPTAC review. Rationale, References, and Websites sections updated.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, Background, References and Websites sections.
Reviewed	02/02/2017	MPTAC review. Updated Websites section.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Description and References.
Reviewed	02/13/2014	MPTAC review.
Reviewed	02/14/2013	MPTAC review. Website updated.
Reviewed	02/16/2012	MPTAC review. Updated Websites.
	01/01/2012	Updated Coding section with 01/01/2012 CPT changes; removed codes 0166T, 0167T deleted 12/31/2011.
New	02/17/2011	MPTAC review. Initial document development. Transferred content addressing Transmyocardial/ Perventricular device closure of ventricular septal defects from SURG.00032.