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CORRESPONDENCE

Research Correspondence

Transcatheter Retrograde Closure of Perimembranous Ventricular Septal Defects in Children With the Amplatzer Duct Occluder II Device

To the Editor: Transcatheter closure of perimembranous ventricular septal defects (pmVSD) is a well-established procedure but is associated with an unacceptable incidence of complete heart block (CHB) (1,2). We describe retrograde single catheter closure of pmVSDs by an off-label use of the Amplatzer duct occluder II (ADO II) device (St. Jude Medical, St. Paul, Minnesota).

All children between 1 and 15 years with pmVSD were included in the initial assessment. The decision to use the ADO II device was based primarily on reduction of the cost of the procedure ($1,500 for device closure) and the need to close symptomatic VSDs in young patients.

Clinical inclusion criteria: At least 3 of the following had to be present:

- Overt heart failure, not improving with medications
- Failure to thrive, predominantly due to hemodynamic effects of the VSD
- Recurrent respiratory infections (defined as >6 events in the preceding 12 months)
- Mid-diastolic flow rumble at the apex on auscultation
- Electrocardiogram showing left atrial enlargement and left ventricular hypertrophy with standard criteria for children
- Cardiothoracic ratio on chest x-ray of >0.55
- Left atrial to aortic diameter ratio on long-axis echocardiogram >1.5
- Left ventricular end-diastolic *z*-score on echocardiogram, indexed to body surface area of >2.0
- Estimated pulmonary to systemic blood flow ratio >1.5 at cardiac catheterization

Morphologic inclusion criteria:

- Isolated pmVSD
- VSD size <6.5 mm
- Upper margin of VSD to aortic valve distance ≥ 3 mm

Morphologic exclusion criteria:

- VSD size >6.5 mm
- Perimembranous VSD with bidirectional or predominantly right to left shunt through the VSD on color Doppler echocardiography
- Perimembranous VSD associated with other structural heart defects requiring surgery

Cardiac catheterization was performed under general anesthesia (n = 12) or intravenous sedation (n = 51), after informed consent was obtained. Intravenous heparin (100 U/kg) was given after femoral arterial access was obtained. Procedures were monitored by transthoracic echocardiography. The diameter of the device is chosen to be either equal to (±0.5 mm) or 1 mm greater than the smallest VSD diameter. A 5-F (internal diameter 0.061 inch) or 6-F (internal diameter 0.070 inch) right coronary artery guiding catheter with side holes (Launcher, Medtronic, Minneapolis, Minnesota; or Cordis, Cordis, Miami Lakes, Florida) was used as the delivery catheter, via the femoral artery. A 0.035-inch or 0.032-inch angulated hydrophilic guidewire (Terumo Corporation, Tokyo, Japan) was used to cross the VSD. The guide catheter was then advanced over the wire into the right ventricle. In a few cases where the delivery catheter took a tortuous course, it was stabilized in the right ventricle by the use of a 0.014-inch "buddy wire" (Galeo Extra Support, Biotronik, Berlin, Germany; or Road Runner, Cook, Inc., Bloomington, Indiana). Where multiple openings were present at >6 mm distance from one another, the procedure was either abandoned (n = 2) or an additional device was used (n = 1) (Fig. 1). All children were given aspirin 3 to 5 mg/kg and clopidogrel 1 mg/kg for 6 months.

Of 63 patients initially assessed (31 male), 57 were eligible for the procedure after left ventricular angiography. Their age ranged from 0.7 to 14.5 years (median 3.7 years), and weight ranged from 7.0 to 31 kg (median 12.5 kg). Median fluoroscopic time was 8.8 (4.0 to 36) min. The median VSD diameter was 5 (3.4 to 6.5) mm. Devices used (device diameter/length in mm) were 4/4 (n = 3), 5/4 (n = 21), 5/6 (n = 3), 6/4 (n = 29), and 6/6 (n = 1). The complete VSD closure rate was 78% immediately after the procedure as documented by left ventricular angiography and transthoracic echocardiography, 92% at 24 h, and 94% at last follow-up. There was 1 device embolization to the pulmonary artery (6/4 mm device), 2 h after the procedure. The device was successfully retrieved, and the defect was successfully closed with a 10-mm Amplatzer muscular VSD occluder. There was no incidence of femoral pulse loss. Fifteen children had tricuspid regurgitation (TR) before the procedure. A reduction of pre-existing TR by at least 2 grades was seen in 11 children after VSD closure; in the other 4 children it was converted to a normotensive (normal calculated RV systolic pressure) TR. Two children developed new trivial aortic regurgitation (AR). One boy who had pre-existing AR associated with valve cusp prolapse underwent device closure with abolition of AR. There was no incidence of left bundle branch block, P-Q prolongation, or CHB during the follow-up evaluation. Most children (n = 46) were underweight before the procedure (less than the third centile for age and sex) and demonstrated appropriate weight gain (with 38 of 45 children—who were followed up for longer than 6 months after VSD closure—reaching weights >10th centile) at follow-up.

Most procedure-related complications have occurred in patients of <6 years of age and/ or weighing <15 kg (3). Post-procedure CHB has been reported to occur in up to 18% of patients undergoing transcatheter closure of a pmVSD under the age of 3 years (4). The longer central waist of the ADO II might avoid mechanical compression of the peri-nodal tissue. The VSDs larger

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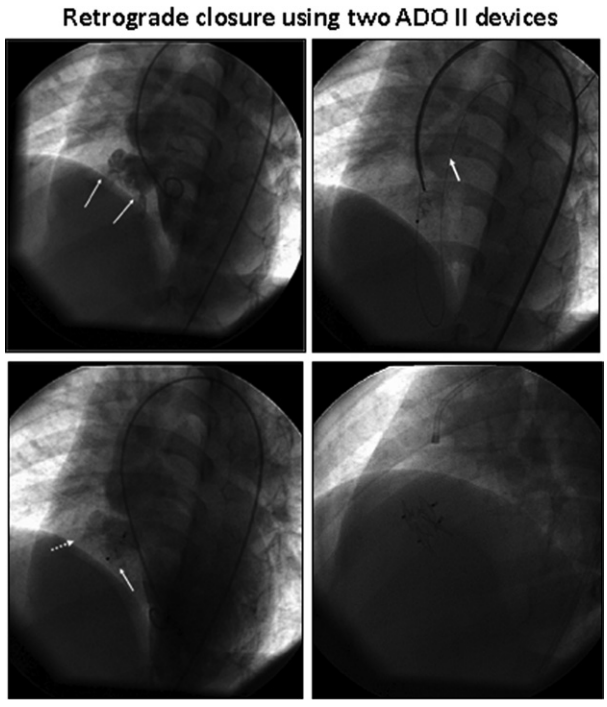

Figure 1 **Membranous Septal Aneurysm With Multiple Fenestrations**

See **arrows, top left panel**. A 0.014-inch guidewire in the pulmonary artery **(arrow, top right panel)** is used to stabilize the delivery catheter during device deployment. A significant residual shunt **(stippled arrow, lower left panel)** is seen, which was closed with a second device **(lower right panel)**. ADO II = Amplatzer duct occluder II (St. Jude Medical, St. Paul, Minnesota).

than 6.5 mm diameter cannot be closed with the ADO II. Because the retention discs are symmetrical, a minimum distance of 3 mm is required between the upper margin of the VSD and the aortic valve. The ADO II device is cheap and effective for closing pmVSDs. Availability of larger-sized ADO II devices might increase its applicability, allowing percutaneous closure of a wider range of VSDs.

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REFERENCES

1. Butera G, Carminati M, Chessa M, et al. Transcatheter closure of perimembranous ventricular septal defects. Early and long-term results. J Am Coll Cardiol 2007;50:1189–95.
2. Carminati M, Butera G, Chessa M, et al. Transcatheter closure of congenital ventricular septal defects: results of the European registry. Eur Heart J 2007;28:2361–8.
3. Bentham JR, Gujral A, Adwani S, Archer N, Wilson N. Does the technique of interventional closure of perimembranous ventricular septal defect reduce the incidence of heart block? Cardiol Young 2011;21:271–80.
4. Predescu D, Chaturvedi R, Friedberg MK, Benson LN, Ozawa A, Lee K-J. Complete heart block associated with device closure of perimembranous ventricular septal defects. J Thorac Cardiovasc Surg 2008;136:1223–8.

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Eligibility for Renal Denervation in Patients With Resistant Hypertension

When Enthusiasm Meets Reality in Real-Life Patients

To the Editor: Percutaneous renal sympathetic denervation (RDN) by radiofrequency ablation is a novel therapeutic intervention that has been shown to decrease blood pressure (BP) significantly (1) and persistently (2) in patients with resistant hypertension (RH). However, the evidence supporting the use of this technique was obtained in a single randomized controlled open trial including 106 patients (1) that has been subject to methodological criticism (3,4). This led the European Society of Hypertension (ESH) to release a position paper that defined strict eligibility criteria for RDN (5). The exact proportion of patients eligible for RDN with the only device currently available (Symplicity, Medtronic, Minneapolis, Minnesota) in "real-life conditions" remains unknown. However, 36 of the 190 patients screened in the Symplicity HTN-2 (Renal Denervation in Patients With Uncontrolled Hypertension) trial (1) did not meet the BP criteria for inclusion, and 30 had a renal artery anatomy incompatible with RDN.

Therefore, we estimated the number of patients eligible for RDN by retrospectively reviewing the computerized medical records of all consecutive patients hospitalized for at least 1 day in 2011 at our tertiary hypertension center at a university hospital in