**Pediatric Cardiology**

# Transcatheter Closure of Muscular Ventricular Septal Defects With the Amplatzer Ventricular Septal Defect Occluder: Initial Clinical Applications in Children

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**OBJECTIVES**     The aim of this study was to close muscular ventricular septal defects (MVSDs) in children, with a new device, the Amplatzer ventricular septal defect occluder (AVSDO).

**BACKGROUND**     The design of previously used devices for transcatheter closure of MVSDs is not ideal for this purpose and their use has been limited by several drawbacks.

**METHODS**     Six patients, aged 3 to 10 years, with MVSDs underwent transcatheter closure using the AVSDO. The device is a modified self-centering and repositionable Amplatzer device that consists of two low profile disks made of Nitinol wire mesh with a 7-mm connecting waist. The prosthesis size (connecting waist diameter) was chosen according to the measured balloon stretched VSD diameters. A 6-F or 7-F sheath was used for the delivery of the AVSDO. Fluoroscopy and transesophageal echocardiography were utilized for optimal guidance.

**RESULTS**     The location of the defect was midmuscular in five patients and beneath the pulmonary valve in one. The balloon stretched MVSD diameter ranged from 6 to 11 mm. Device placement was successful in all patients, and complete occlusion occurred in all six patients (95% confidence interval 54.06% to 100%). Two patients developed transient complete left bundle branch block. No other complications were observed.

**CONCLUSIONS**     This encouraging initial clinical success indicates that the AVSDO is a promising device for transcatheter closure of MVSDs in children. Further clinical trials and longer follow-up are needed before the widespread use of this technique can be recommended.  (J Am Coll Cardiol 1999;33:1395–9) © 1999 by the American College of Cardiology

Surgical repair of congenital muscular ventricular septal defects (MVSDs) has been associated with considerable morbidity and mortality (1). As an alternative to surgery a variety of devices have been used for transcatheter closure of congenital or postmyocardial infarction MVSDs (2–5). However, these devices were not originally designed for this purpose, and their widespread use has been limited by several drawbacks such as large delivery sheaths, inability to recapture and reposition and a very high rate of residual shunts (2–4). The Amplatzer ventricular septal occluder is a new device especially designed for transcatheter closure of defects of the muscular ventricular septum which has been successfully tested in animal and in vivo experimental studies (6). In this report we present the first clinical applications in children.

## METHODS

**Device design.** The presented device is a modified Amplatzer atrial septal defect (ASD) occluder (7,8), which is self-centering and repositionable after deployment and has a low profile. It is constructed of 0.004-in. (0.01 cm) Nitinol wires, tightly woven into two self-expandable flat round disks with a 7-mm connecting waist corresponding approximately to the thickness of the muscular ventricular septum (Fig. 1). Dacron fabric is sewn into both retention disks as well as into the waist. Waist diameters vary from 6 to 14 mm. The left ventricular retention skirt is 4 mm larger than the waist, and the right ventricular retention skirt is only 3 mm larger than the waist. The device is securely fastened onto a delivery cable by a recessed screw. It is

loaded into a long 6-F or 7-F (occluders larger than 6 mm) delivery sheath.

**Patient population.** Between November 1997 and May 1998, six patients aged 3 to 10 years with MVSDs were subjected to transcatheter closure with the Amplatzer muscular VSD occluder (AGA Medical Corporation, Golden Valley, Minnesota). In all patients VSD closure was indicated for hemodynamic or other medical reasons. Informed consent was obtained in each case, and devices were implanted under a research protocol approved by the Ethical Committee of "Aghia Sophia" Children's Hospital of Athens.
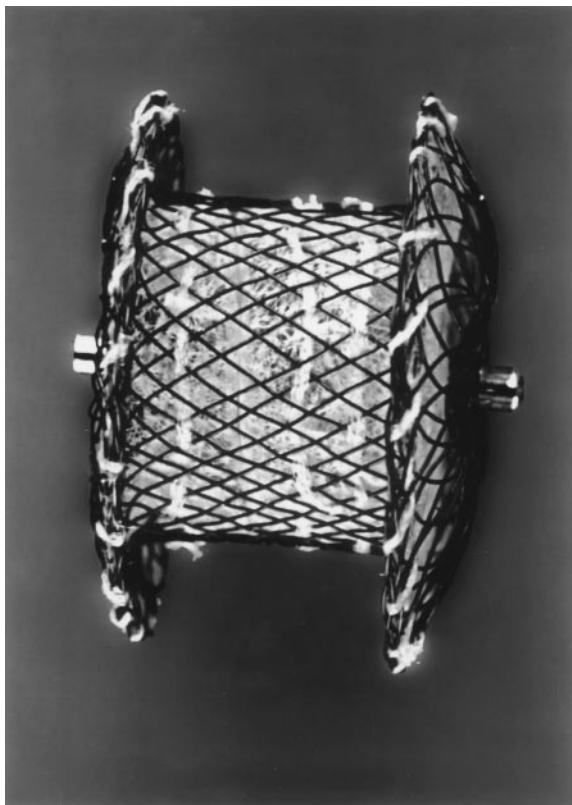


**Figure 2.** Steps of transcatheter muscular ventricular septal defect closure with modified Amplatz device. **(A)** Long axial oblique left ventriculogram obtained from Patient 4, demonstrating a midmuscular ventricular septal defect **(arrowheads)**. **(B)** Hand injection of contrast medium into the left ventricle showing an appropriately positioned left ventricular disk. **(C)** Deployment of the right ventricular disk. **(D)** Long axial oblique left ventriculogram after release of the device, showing complete closure of the defect.



**Figure 1.** Side view of the Amplatzer muscular ventricular septal defect occluder made of woven 0.004-in. (0.01 cm) Nitinol wires into two flat disks with a 7-mm connecting waist. The left ventricular disk is on the right and the right ventricular disk is on the left of the panel.
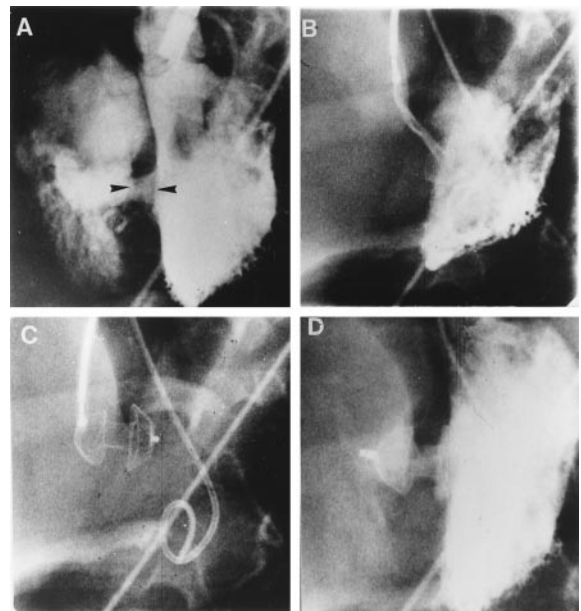
**Study design.** Patients were screened by conventional transthoracic two-dimensional echocardiography with multiple subxyphoid, apical and parasternal views. Two patients with suboptimal transthoracic echocardiographic examination were further evaluated with biplane transesophageal and color Doppler echocardiography. Two patients had undergone diagnostic cardiac catheterization and angiography three and six months before transcatheter closure. Patient inclusion criteria were: a) maximal VSD diameter less than 12 mm; b) a distance of >5 mm from the margins of the defect to the aortic, mitral and tricuspid valves; c) single or main central (in cases of multiple Swiss cheese type defects) opening into the right ventricular cavity, and d) left to right shunt across the defect with left ventricular enlargement.

**Procedure.** The technique of transcatheter closure of MVSDs used was similar to that described by Lock et al. (2,3). The patients were intubated and under general anesthesia underwent right and left heart catheterization. The location and size, number of defects and their relation to the surrounding structures were defined by angled angiographic views. Five patients had a single midmuscular (Fig. 2A) and one patient an outlet muscular (Fig. 3A) VSD. In the five patients with the midmuscular VSDs a retrograde arterial catheter (4 to 5 F Cobra type I, Cordis) was passed from the left ventricle to right ventricle. This was facilitated by small hand injections of contrast medium, through a second arterial catheter (4- to 5-F Pigtail, Gordis) that was
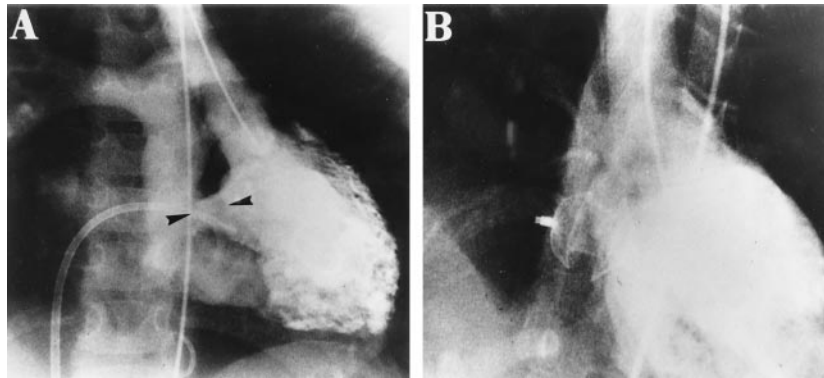
**Figure 3.** Left ventriculogram in a four-chamber view obtained from patient 1 with corrected transposition of the great arteries and an outlet ventricular septal defect **(arrowheads),** before **(A)** and after **(B)** device placement. Complete closure of the defect has been achieved.

introduced from the opposite femoral artery. Through the Cobra catheter a soft J-tipped 260-cm exchange 0.032- to 0.035-in. (0.08 to 0.09 cm) guide wire was advanced into the pulmonary artery, where it was snared from a percutaneous jugular approach. Then the catheter was removed and a 7-F (6 F in one patient) long transseptal sheath was advanced over the wire from the jugular vein to the left ventricle. In the patient with the outlet VSD a 7-F balloon-tipped end-hole catheter was introduced into the right ventricle from the femoral vein and exchanged for the 7-F delivery sheath. All patients underwent balloon sizing to establish the "stretched" diameter of the defect (2). The device size (waist diameter) was selected to be equal to the measured "stretched" diameter (2). The device was screwed to the tip of the delivery cable and collapsed into a loader as previously described (7,8). The collapsed device was then

advanced into the guiding catheter by pushing the delivery cable. Under fluoroscopic and transesophageal ultrasonic guidance, the left ventricular disk was deployed and pulled gently against the septum, which was both felt and observed by transesophageal echocardiography (TEE) and angiocardiography (Fig. 2B). Then the sheath was pulled back and the right ventricular disk was deployed (Fig. 2C). The device was released only when its position was optimal and interference with atrioventricular valve structures had been excluded by TEE with color flow Doppler (Fig. 4). After release of the device both color Doppler echocardiography and left ventriculography were performed to detect residual shunts (Figs. 2D and 3B). All patients were discharged on the day after the procedure on aspirin 3 to 5 mg/kg daily for six months.

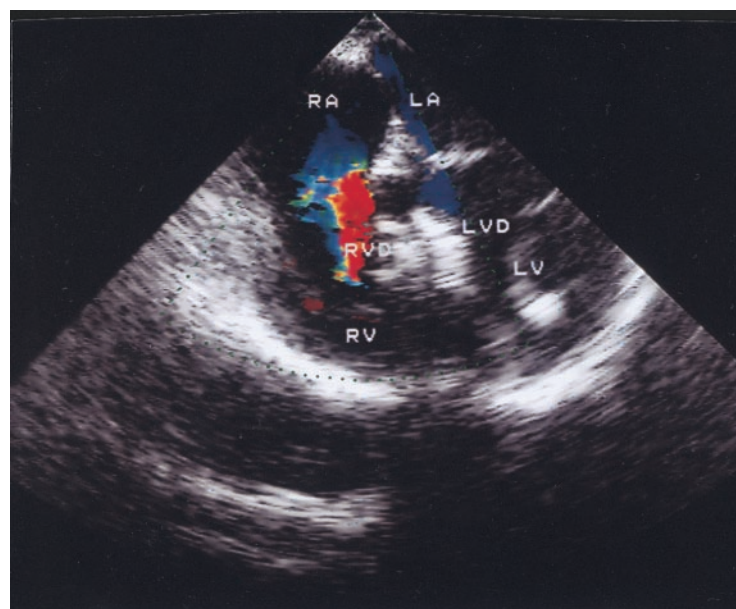All patients had a chest X-ray and a transthoracic color



**Figure 4.** Transesophageal two-dimensional and color Doppler obtained from four-chamber view immediately after implantation of the Amplatzer prosthesis. Note good position of the device with no evidence of residual shunt. LA = left atrium; LV = left ventricle; LVD = left ventricular disk; RA = right atrium; RV = right ventricle; RVD = right ventricular disk.

**Table 1.** Patient Characteristics and Outcome After Device Placement

| Patient No. | Age (yr) | Weight (kg) | Diagnosis | "Stretched" VSD Diameter (mm) | Outcome | Complications |
|---|---|---|---|---|---|---|
| 1 | 3 | 14 | CTGA, SubPS, outlet VSD | 11 | Complete closure | TCLBBB |
| 2 | 3.5 | 15 | Midmuscular VSD | 11 | Complete closure | TCLBBB |
| 3 | 5 | 18 | Midmuscular VSD | 6 | Complete closure | None |
| 4 | 10 | 33 | Midmuscular VSD | 11 | Complete closure | None |
| 5 | 7 | 30 | Midmuscular VSD | 8 | Complete closure | None |
| 6 | 6 | 25 | Midmuscular VSD | 9 | Complete closure | None |

CTGA = corrected transposition of the great arteries; SubPS = subpulmonary stenosis; TCLBBB = transient complete left bundle branch block; VSD = ventricular septal defect.

Doppler echocardiographic study at 24 h after the procedure and at 1 and 3 months later. A transesophageal echocardiographic study was scheduled for the 6-month follow-up. Persistent shunts were angiocardiographically and echocardiographically graded as foaming, trivial, small, moderate and large as previously described (7,8).

## RESULTS

Patient characteristics and outcome after device placement are summarized in Table 1. The balloon "stretched" diameters ranged from 6 to 11 mm (mean = 9.3). The angiographic defect diameters ranged from 5 to 9 mm (mean = 7.3) and the thickness of the muscular ventricular septum from 5 to 6.5 mm (mean = 5.5). Pulmonary/systemic flow ratio (Qp/Qs) varied from 1.7 to 2.5 (mean = 2.1). Systolic pulmonary artery pressure (SPAP) was normal in all patients with midmuscular VSDs. Patient 1 had corrected transposition of the great arteries (TGA) with an outlet VSD, but despite the presence of a mild to moderate subpulmonary stenosis (peak systolic pressure gradient = 40 mm Hg) he had a significant left to right shunt (Qp/Qs = 2.2:1) and a SPAP of 60 mm Hg. After administration of 100% oxygen, the SPAP was reduced to 40 mm Hg and the Qp/Qs increased to 2.7:1. Patient 3 had a small to moderate VSD (Qp/Qs = 1.7) and two episodes of subacute infective endocarditis. During the last episode he had a suspected cerebral embolic event with emesis and severe headache. Surgical closure was suggested after this episode, but it was refused by the parents.

Device delivery was successful and associated with complete occlusion in all six patients (100% closure rate, 95% confidence interval 54.06% to 100%) (Figs. 2D and 3B). Foaming was present in two patients but disappeared within 15 to 20 min. Misplacement of one disk into the right ventricle occurred in one patient and was successfully managed by recapturing the device in the delivery sheath and redeploying it. During the procedure two patients developed complete left bundle branch block, which resolved within 12 h. No other complications were observed. Fluoroscopy and total procedural times ranged from 34 to 57 min (mean = 47 min) and from 122 to 155 min (mean = 138 min), respectively.

Follow-up echocardiographic data were available in all six patients at one and three months after the procedure. There was no evidence of residual shunts. The device was in an appropriate position and no interference with the adjacent cardiac structures was observed. Metal fatigue fractures on chest radiography were not observed. The patient with the corrected TGA and the outlet VSD underwent cardiac catheterization three months after the transcatheter closure which showed a normal for age pulmonary artery pressure (35 mm Hg) and a peak subpulmonary pressure gradient of 35 mm Hg. Angiography did not reveal an increase of the subpulmonary obstruction.

## DISCUSSION

Transcatheter closure of MVSDs with the Rashkind double umbrella was first described by Lock et al. in 1988 (2). Subsequently, the Lock clamshell occluder (3,4) and very recently the Sideris buttoned device (5) have been used for nonsurgical closure of MVSDs, but have not always performed at their expectations. The Rashkind double umbrella was originally designed for closure of a persistent patent ductus arteriosus and the clamshell occluder as well as the buttoned device for occlusion of ASDs. Therefore, their shape and design are not ideal for transcatheter closure of MVSDs. The major limitations of these devices include large delivery systems limiting their use in infancy with risk for vascular injury, complex implantation techniques, inability of repositioning and redeployment and significant residual shunts (3–5). Kumar et al. reported his experience with closure of apical muscular VSDs in 10 patients using the clamshell device and the incidence of residual shunts was 100% (4). Apparently the umbrella type device does not provide complete closure.

**Comparison with other devices.** The findings of this study, which represents the first human experience, indicate that transcatheter closure of single MVSDs with the Amplatzer VSD occluder is feasible, effective and safe. Complete occlusion was obtained in all patients with no significant complications during the procedure or at short-term follow-up. The device used is a novel modification of the Amplatzer ASD occluder which offers significant advantages over the previously used devices: 1) it is delivered

through a 6- to 7-F sheath, which allows its use even in small infants; 2) its long connecting waist fits within the communication forcing the blood to pass through a channel filled with thrombogenic polyester material, and therefore closure by thrombosis should be virtually 100%; 3) it possesses low profile small retention disks to lower the risk of encroachment on vital cardiac structures, and 4) it can be easily repositioned and redeployed several times. Although we did not encounter all anatomic types of MVSDs, such as apical or multiple defects, we believe that these communications will be amenable to transcatheter closure with this device. The other issue to be addressed is the thickness of the muscular ventricular septum. Based on measurements we previously made in normal hearts the diameter of most muscular ventricular septa varied from 4 to 6.5 mm (unpublished data). Therefore, the 7-mm standard waist length of the Amplatzer VSD occluder is suitable for the vast majority of the patients. If the device protrudes slightly into the ventricles it is completely immaterial as full endothelialization will occur. However, septa much thicker than 7 mm would be unsuitable until modifications of the prosthesis are available. No patient in this study had a ventricular septal thickness greater than 7 mm, in which case it would potentially cause problems of overelongation of the device.

Precise measurement of the defect size is critical for successful closure. Since the anatomy of several MVSDs is complex the echocardiographic and angiographic estimation of the defect diameter may be misleading. Typically these defects change their size during systole and diastole and are therefore difficult to measure. Therefore, the selection of the device diameter according to the balloon "stretched" diameter of the MVSD is of paramount importance to achieve complete occlusion and prevent device dislodgement and embolization. This maneuver also allows precise localization of the communication and reconfirms catheter passage through its main channel (2). Nevertheless, echocardiographic evaluation before closure remains essential to map the VSD location, demonstrate additional defects and determine the overall suitability for transcatheter closure. Transesophageal and color Doppler echocardiography play a very important role in guiding the deployment of the device and the assessment of results (9).

**Conclusions.** The Amplatzer VSD occluder appears to be a promising device for the transcatheter closure of MVSDs in children. But before this technique enters routine clinical practice, further studies are required to document its efficacy, safety and long-term results in a larger number of patients.

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