BRIEF COMMUNICATIONS

INTRAOPERATIVE CLOSURE OF MUSCULAR VENTRICULAR SEPTAL DEFECT IN A CANINE MODEL AND APPLICATION OF THE TECHNIQUE IN A BABY

Zahid Amin, MD, James M. Berry, RDMS, John E. Foker, MD, Albert P. Rocchini, MD, and John L. Bass, MD, Minneapolis, Minn., and Chicago, Ill.

Isolated muscular ventricular septal defects (VSDs) account for 10% of VSDs. Among these, inlet and mid-muscular VSDs are relatively easy to approach surgically, but apical and anterior muscular VSDs can be difficult to visualize during the operation.^{1,2} Intraoperative closure of muscular VSDs with a device during cardiopulmonary bypass (CPB) has been described with good results.³ The current report describes the use of a new transcatheter device to close muscular VSDs intraoperatively without using CPB in three dogs and later in an 8-month-old girl.

Animal studies. The Amplatz VSD device (AGA Medical Corporation, Golden Valley, Minn.) is a modified version of the Amplatz septal occlusion device.⁴ It is made of fine nitinol wires that are woven into two discs with a connecting waist. The discs are filled with polyester to enhance thrombogenicity. The device is custom built to correspond to the size of the VSD and thickness of the ventricular septum. It has a screw mechanism on one side for connection to the delivery cable. The device is withdrawn into a loader before introduction into the delivery sheath.

All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" (NIH Publication No. 86-23, revised 1985). The study protocol was approved by institutional animal care committee of the University of Minnesota.

To determine the feasibility of intraoperatively closing muscular VSDs, we created an anterior or apical VSD in three dogs with the help of a punch device. The diameter of the punch device was 10 mm.

With the animal under general endotracheal anesthesia and aseptic technique, the chest was entered by median sternotomy. The pericardium was opened. Two stay

stitches were applied on the right ventricular free wall. A purse-string suture was placed on the left atrial appendage. The index finger of the left hand was inserted in the left atrium and advanced in the left ventricle. A right ventriculotomy was performed and the punch device inserted through the incision in the right ventricle. With a burring action, the septum was traversed until the punch device touched the index finger in the left ventricle. The punch was locked and removed, and the right ventriculotomy was closed with 5-0 running Prolene suture (Ethicon, Inc., Somerville, N.J.). The size of the defect was measured by epicardial echocardiography. In one dog two VSDs were created. An Amplatz VSD device that corresponded to the size of the VSD was screwed onto the delivery cable and withdrawn with the delivery sheath immersed in saline solution to avoid entrapment of air bubbles. The sheath was pushed through the right ventricular free wall. With the aid of epicardial echocardiographic guidance the sheath was aimed toward the muscular VSD. Once the sheath was across the VSD, the left disc was deployed in the left ventricle. The sheath was withdrawn and the right disc deployed in the right ventricle. The device was disconnected from the cable by counterclockwise rotation of the cable. Residual shunt was checked with the help of epicardial echocardiography.

Results. A total of four VSDs were created in three dogs. The smallest measured 7 mm and the largest 11 mm. Three muscular VSDs were closed during the operation and the fourth one in the catheterization laboratory. The first dog died 2 hours after the operation because of ventricular fibrillation. Dissection of the heart revealed the device in good position. The second dog was put to death after 3 months. Examination of the heart revealed the device in the optimal location with complete endothelialization. The third dog (with two devices) is still alive. Six months' follow-up echocardiogram and angiogram revealed no shunt.

Muscular VSDs in an 8-month-old baby. The operation was done on the basis of compassionate need. Informed consent and approval of the Institutional Review Board of the University of Minnesota, Minneapolis, were obtained before placement of the device.

Baby A was born with multiple muscular VSDs (anterior and apical muscular) and coarctation of aorta. She underwent repair of aortic coarctation and pulmonary artery banding on the fourth day of life. At the age of 8 months she had debanding with closure of large muscular VSDs. Postoperatively a significant residual shunt was identified, but the VSD could not be located during CPB.

From the Departments of Cardiology and Cardiovascular Surgery, University of Minnesota, Minneapolis, Minn., and Department of Cardiology, Children's Memorial Medical Center, Northwestern University Medical School, Chicago, Ill.

Received for publication Oct. 27, 1997; revisions requested Nov. 5, 1997; revisions received Nov. 20, 1997; accepted for publication Nov. 20, 1997.

Address for reprints: Zahid Amin, MD, Children's Memorial Medical Center, Cardiology, Box 21, 2300 Children's Plaza, Chicago, IL 60614.

J Thorac Cardiovasc Surg 1998;115:1374-6

Copyright © 1998 by Mosby, Inc.

0022-5223/98 \$5.00 + 0 12/54/87804

Fig. 1. Schematic diagram illustrating the steps involved in deployment of the device through the right ventricular free wall. *RV*, Right ventricle; *LV*, left ventricle; *MPA*, main pulmonary artery; *Ao*, aorta; *SVC*, superior vena cava; *TV*, tricuspid valve; *RA*, right atrium; *IVC*, inferior vena cava.

The baby was transferred to the intensive care unit. Several attempts were made to wean her from the ventilator but were unsuccessful. Cardiac catheterization revealed a large ($>2:1$) shunt.

Attempts were made to close the defect in the catheterization laboratory, but the procedure was unsuccessful because the defect could not be crossed with the wire. The baby was brought back to the operating room. A median sternotomy was performed and the size of the VSD measured by epicardial echocardiography ($15 \text{ mm} \times 3 \text{ mm}$). With the heart beating, a 7F sheath was introduced through the right ventricular free wall. The sheath was guided across the defect with the aid of epicardial echocardiography. The device was deployed as described earlier. There was no shunt by epicardial echocardiography after the deployment. Serial transthoracic echocardiograms obtained while the patient was in the intensive care unit revealed complete closure of the VSD. The baby was extubated 8 days later.

Discussion. Muscular VSDs are difficult to close and have a high incidence of residual VSD, leading to multiple operations and increased morbidity and mortality. Left ventriculotomy has been advocated in the past but may lead to left ventricular dysfunction.² This is the first report that describes intraoperative closure of VSDs without the use of CPB with the Amplatz VSD device. This technique may be valuable in small infants in whom catheter manipulation is difficult. The advantages of the modified Amplatz device include complete retrievability, self-centering, small delivery system, malleability, and availability in

Fig. 2. Schematic cross-sectional epicardial echocardiogram still frames showing the deployment of the device in the baby. **A**, A 7F sheath across the VSD (black arrows). **B**, Deployment of the left disc. **C**, Complete deployment of the Amplatz VSD device (white arrow).

several sizes. After successful animal studies,⁵ more clinical trials are warranted.

REFERENCES

1. Kirklin JK, Castaneda AR, Keane JF, Fellows KE, Norwood WI. Surgical management of multiple ventricular septal defects. *J Thorac Cardiovasc Surg* 1980;80:485-93.

2. Serraf A, Lacour-Gayet F, Bruniaux J, Ouaknine R, Losay J, Petit J, et al. Surgical management of isolated multiple ventricular septal defects. *J Thorac Cardiovasc Surg* 1992;103:437-43.
 3. Fishberger SB, Bridges ND, Keane JF, Hanley FL, Jonas RA, Meyer JE, et al. Intraoperative device closure of ventricular septal defects. *Circulation* 1993;88(Pt 2):205-9.
 4. Sharafuddin MJ, Gu X, Titus JL, Urness M, Cervera-Ceballos JJ, Amplatz K. Transvenous closure of secundum atrial septal defects. *Circulation* 1997;95:2162-8.
 5. Amin Z, Gu X, Berry JM, Bass, JL, Urness M, Titus JL, et al. A new device for closure of muscular ventricular septal defects in a canine model [abstract]. *Circulation* 1997;96(Suppl):I373.
-