Pediatric Interventions

A Late Complication With the CardioSEAL ASD Occluder Device and Need for Surgical Revision

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A late complication of the CardioSEAL atrial septal defect (ASD) occluder is reported. Although left atrial umbrella was completely epithelialized and occluded ASD without residual defect; the right atrial umbrella protruded toward the center of right atrium after 18 months. We believe this may be associated with the structural abnormality of the device. Cathet Cardiovasc Intervent 2001;54:335-338. © 2001 Wiley-Liss, Inc.

Key words: transcatheter; ASD closure; children

INTRODUCTION

Transcatheter nonsurgical closure of atrial septal defect (ASD) is an alternative to operative repair. It is estimated that approximately half of all patients with secundum ASDs are suitable candidates for nonsurgical closure [1]. Many transcatheter closure techniques and devices have been developed in the past 20 years. Each device has its own advantages and disadvantages; not surprisingly, a variety of problems have been encountered with each system [2]. One of these devices is the CardioSEAL septal occluder, which is a second-generation device, the improved and refined version of the double umbrella device (Clamshell occluder) due to high rate of arm fractures in long-term follow-up [3,4]. Although the refined and redesigned form of Clamshell occluder, namely the CardioSEAL occluder, had fewer complications, the reported cases of one or more arm fractures, embolizations, or thrombosis are not infrequent. We report a previously unmentioned late complication of the CardioSEAL ASD occluder device, the protrusion of the right atrial umbrella toward the right atrium and the tricuspid valve.

CASE REPORT

A 13-year-old young male (body weight, 58 kg; height, 172 cm), who had a 2/6 mid systolic murmur best heard at the pulmonary region and fixed split second heart sound, was evaluated in the pediatric cardiology department. The ECG was unremarkable except for the incomplete right bundle branch block; the chest X-ray revealed normal cardiac silhouette and normal pulmonary vascular appearance. Transesophageal echocardiography (TTE) demonstrated a 10 mm secundum ASD and paradoxical septal motion with slight enlargement of right ventricle and atrium. A right and left heart catheterization was performed under general anesthesia with continuous transesophageal echocardiographic (TEE) monitoring. On TEE, the maximal ASD diameter and the length of the interatrial septum were 11 mm and 38 mm, respectively. Distance from AV valves (the anterior rim), superior caval vein, inferior caval vein, right upper pulmonary vein, and coronary sinus to defect were 12, 14, 12, 14, and 9 mm, respectively. The saturation data indicated a pulmonary to systemic flow (Qp/Qs) ratio of 2.6:1 with a 25 mm Hg systolic pulmonary arterial pressure. Stretched diameter of the ASD measured by the maximum balloon diameter occluding the defect was 15 mm; 28 mm CardioSEAL (Nitinol Med Tech, Boston, MA) device was selected to occlude the ASD. The collapsed CardioSEAL ASD occluder device and 11 Fr sheath as a unit were positioned on the left atrial side of

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the defect. By partially pulling back the sheath, the left atrial umbrella was opened. The system was retracted to bring at least one arm into slight contact with the septum. The sheath was pulled back further to allow it to open the right atrial umbrella. After confirmation of appropriate arm and device position by TEE, the device was released. A trivial (minimal jet less than 1 cm of color disturbance on the right atrial side) residual shunting was detected by color flow TEE study. No complication was observed during and immediately after implantation. Heparin 100 U/kg and prophylactic antibiotic was administered at the beginning of the procedure. Heparinization was continued for the first 24 hr after procedure. Aspirin (2-3 mg/kg/day) and prophylaxis for bacterial endocarditis were recommended for 6 month after implantation. Patient was discharged from hospital the day after the procedure. Before discharge, clinical evaluation, chest X-ray, ECG, and TTE were performed. The initial trivial residual shunt seen immediately after implantation had disappeared on the day of discharge. Regular follow-up in the 1st, 6th, 12th, and 18th month after the closure were performed. Holter monitoring was additionally performed in the first month. Until his last visit, the patient had no complaints and complications such as device embolization, thromboembolic event, pericardial effu-
sion, systemic or pulmonary venous obstruction, rhythm disturbances, or impaired atrioventricular (AV) valve function were observed during follow-up. At the last visit, which was 18 months after the implantation, on TTE examination the right atrial umbrella was displaced 18–20 mm away from the septum and was protruding toward the center of right atrium. There was no thrombus formation on device or in the atria (Fig. 1). There was no contact between the interatrial septum and the arms of the right atrial umbrella. On two-dimensional and color Doppler TEE study, one arm of the right atrial umbrella overhung into tricuspid valve orifice (Fig. 2) and stroke the valve during each systole. Left atrial umbrella was in good position and there was no residual shunt. The center of the left-side umbrella was also slightly displaced from the left to right atrium (Fig. 3). No AV valve insufficiency was observed. The cross-sectional view of the CardioSEAL ASD occluder device is schematically shown in Figure 4. An operation was planned for removal of the device and surgical closure of the ASD. The device was examined during the operation and complete epithelialization was detected on the left atrial umbrella. The left atrial umbrella was in good position, occluding the ASD without any residual defect. The right atrial umbrella was extending from the surface of the interatrial septum and had the appearance of a flower (Fig. 5). Neither significant epithelialization nor thrombus formation was observed on the right atrial umbrella (Fig. 6). All the arms of the device both on the right side and on the left side were intact (Fig. 6).

**DISCUSSION**

Long-term follow-up studies concerning the patients with isolated secundum ASD occluded with the Clamshell device demonstrated arm fractures in up to 84% of the patients within the first year of the implantation and they were possibly associated up to 2% of the cases with recurrent shunts, late embolizations, or development of small fibrotic masses on the atrial wall [5–7]. Intensive engineering evaluation of the device demonstrated that the metal used in the structure was brittle enough and easily fractured when it was subjected to mild flexion forces in the beating heart [5]. Therefore, the device was redesigned to lessen the possibility of the arm fractures while maintaining its original concept. The type of the metal used to construct in the new device, namely the CardioSEAL, was an alloy (MP35N) that was far superior than the formulation used in the Clamshell. These changes also provided a better final device configuration, when it sprang back from its folded position in the delivery catheter [5].

Kaulitz et al. [8] reported their experience with transcatheter ASD closure with the CardioSEAL device in seven selected patients who presented with various morphologies of the atrial septal defects. No complications or serious arrhythmias were observed during the short period of follow-up (median, 1.8 months). In a European multicenter trial, transcatheter ASD closure was performed in 96 patients using the CardioSEAL device. In a mean follow-up period of 5.3 months, two patients suf-
ferred device embolization, and silent fracture of an arm of the device was observed in six patients [9]. Contrasting the optimistic results, the preliminary data from several U.S. centers suggest that the early problems of arm fracture, device embolization, and residual shunt remain significant issues [10]. In another study, 25 ASD occlusions with the CardioSEAL device were attempted by Eiken et al. [11]. However, the procedure was not completed in two patients, and the device was withdrawn back into the sheath due to significant residual shunt [11]. In another patient, the device had to be removed surgically due to incomplete occlusion of the ASD and significant shunt [11].

In our patient, after a successful implantation and good positioning of the CardioSEAL device, there was no residual shunt. However, we observed a late complication after 18 months of implantation, which was not mentioned in literature before. Although the device had sprung back to the intended device configuration at the time of implantation, the original configuration could not be maintained. The device had intact arms, but was deformed in time as schematized in Figure 4. We guess that this complication may be due to the structural abnormality of this device and that this device was originally defective.

REFERENCES