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Case Report

Transcatheter closure of perimembranous ventricular septal defects with Amplatzer® duct occluder I; The first case report in Japan

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ABSTRACT

We report the first case of transcatheter perimembranous ventricular septal defect (pmVSD) closure in Japan where none of existing devices for VSD closure has been approved. The pmVSD was successfully closed with first generation Amplatzer® duct occluder (ADO-I; St Jude Medical, St Paul, MN, USA). The procedure was performed under general anesthesia with transesophageal echocardiographic and fluoroscopic guidance. The left ventricular volume overload after the procedure was remarkably improved and no major complications occurred. ADO-I can be a safe and effective option for transcatheter pmVSD closure. The incidence of heart block may be less than reported with the original device.

<**Learning objective:** Use of Amplatzer® duct occluder is effective in transcatheter perimembranous ventricular septal defect (pmVSD) closure in selected patients. It may be safer than original Amplatzer pmVSD occluder to avoid complete atrioventricular block.>

Introduction

Although Amplatzer® perimembranous ventricular septal defect (pmVSD) occluder (St Jude Medical, St Paul, MN, USA) was introduced for transcatheter closure of pmVSD in 2003, the high incidence of complete heart block was reported (5.7%) later on [1]. According to the results, the American Heart Association has not recommended transcatheter device closure of pmVSD [2]. However, the utility of pmVSD occluding devices is being tested internationally and various devices for pmVSD have been developed worldwide. In Japan, although transcatheter coil occlusion of pmVSD was reported in 2008 [3], this procedure is no longer used because of the complexity of the procedure and unavailability of 0.052 inch coil. There are some reports that reported safety and effectiveness of device closure of pmVSD with first generation Amplatzer® duct occluder (ADO-I) [4–6]. However, its safety and outcome have not been fully investigated.

Case report

The patient was a 13-year-old boy, weight was 42.9 kg and height was 157 cm. Transthoracic echocardiography showed remarkable left ventricular volume overload. The defect size was 5.7 mm and 7.0 mm at right ventricular (RV) and left ventricular (LV) side, respectively. The distance between margin of defect and non-coronary cusp of the aortic valve was 5.8 mm (Fig. 1). After explanations about advantages and risks of a surgical and a transcatheter ventricular septal defect (VSD) closure, informed written consent was obtained. The protocol of the procedure was planned to be applied to patients who fulfill the inclusion and exclusion criteria, the details are mentioned in the discussion, and approved by the Ethics Committee of Showa University School of Medicine.

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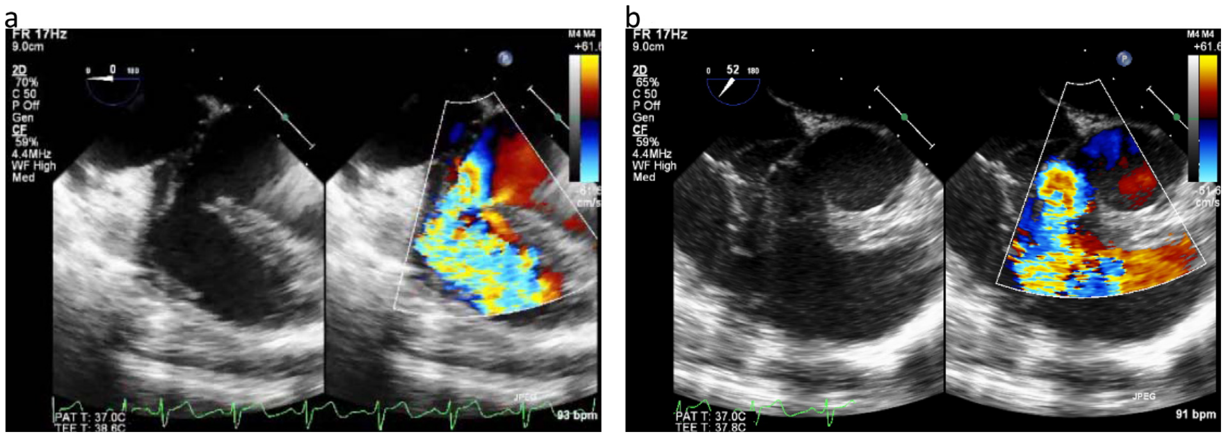

Fig. 1. Ventricular septal defect on the transesophageal echocardiography at angle of 0° (a) and 52° (b).

After femoral venous and arterial access has been obtained, routine diagnostic catheterization was performed. Qp/Qs was 1.9 and Rp was 0.8 wood units. The LV end-diastolic volume was 174% of normal. Left ventriculogram in the 30° left anterior oblique projection with 30° cranial angulation showed the VSD, the size of the defects was 4.9 mm and 11.2 mm at the RV and LV side, respectively (Fig. 2a). We decided to use the first-generation ADO-I of 10/8 mm. After ventriculography, the defect was crossed by using a hydrophilic 0.035 angled tip guide wire (Terumo, Tokyo, Japan) via 4Fr right Judkins diagnostic catheter from the LV side. Then the wire was advanced to the pulmonary artery (Fig. 2b). A wedge pressure catheter directed into the main pulmonary artery via the femoral vein was exchanged over the wire for a snare catheter. The guide wire was snared by 15 mm Amplatz Goose Neck Snare (Microvena, White Bear Lake, MN, USA) in pulmonary artery and arteriovenous wire loop was established through the defect (Fig. 2c). Using the established arteriovenous wire loop, 7Fr TorqVue delivery system (St. Jude Medical, Inc.) was advanced from

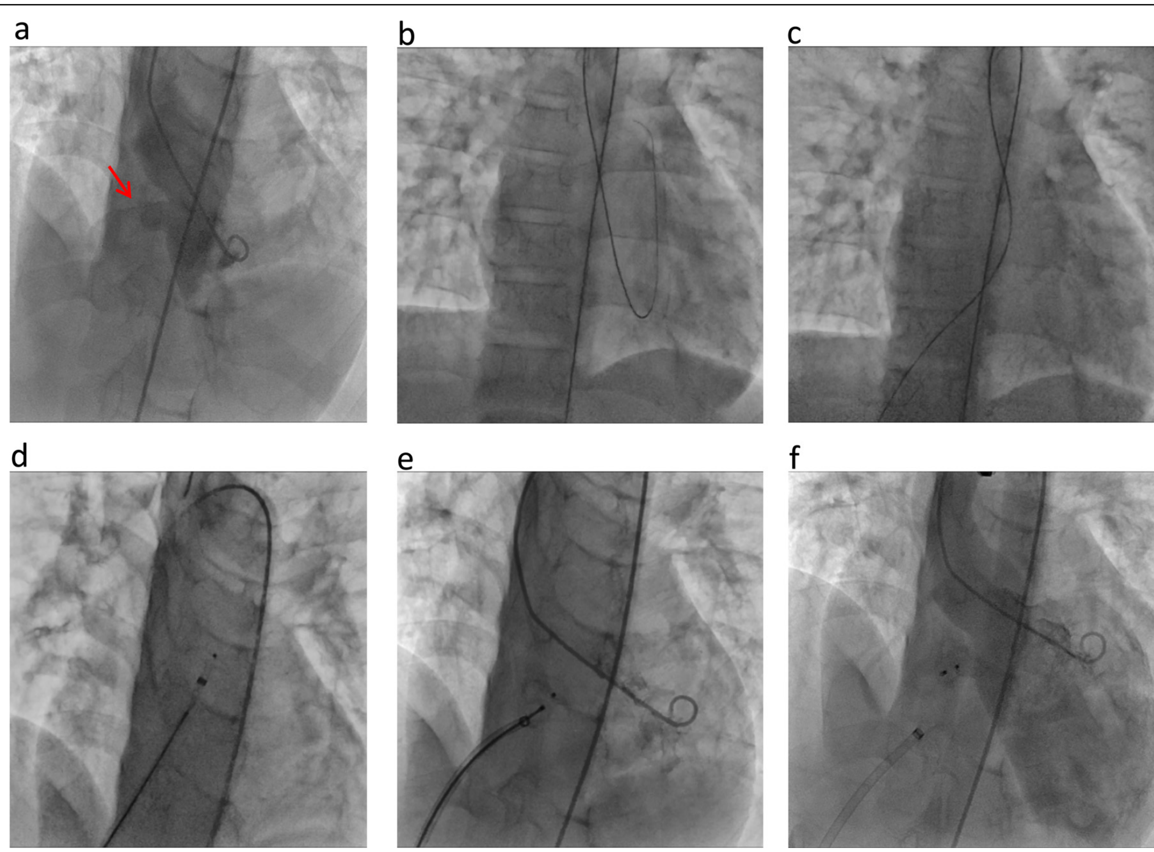

Fig. 2. (a) Left ventriculogram in the 30° left anterior oblique (LAO) projection with 30° cranial angulation showed the ventricular septal defect (arrow). (b) The defect was crossed from the left ventricular side by using a hydrophilic 0.035 angled tip guide wire via 4Fr right Judkins diagnostic catheter. (c) The arteriovenous wire loop was established through the defect. (d) The retention disc of ADO-I was deployed in the ascending aorta. (e) The superior edge of the retention disc was deployed inside the ampulla and the inferior edge of the disc was still on the left ventricle aspect. (f) Post-deployment angiogram.

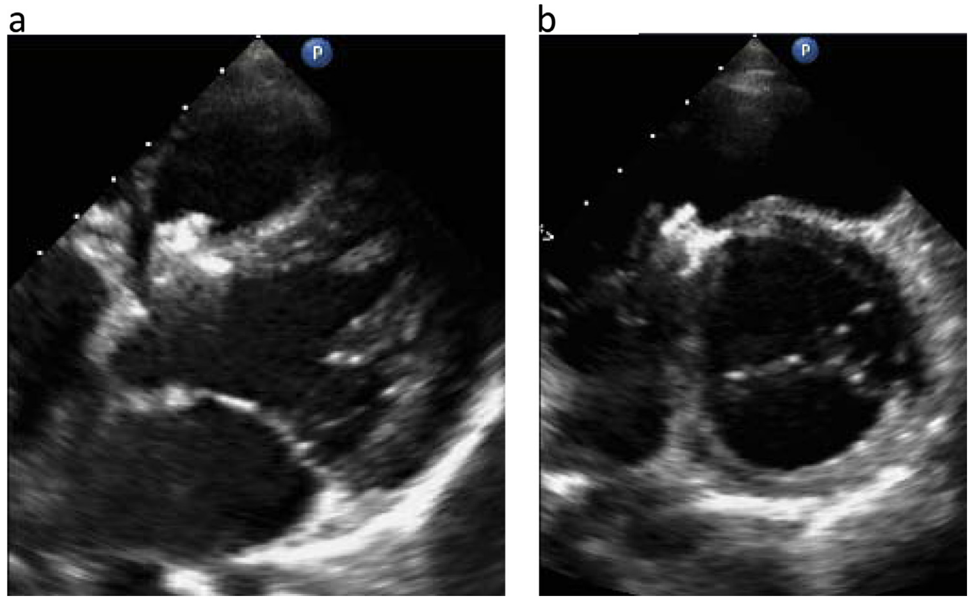

Fig. 3. Transthoracic echocardiography after the procedure at four-chamber view (a) and short-axis view (b).

venous side into the ascending aorta through the defect. The retention disc of ADO-I was deployed in the ascending aorta and pulled back carefully to the LV through the aortic valve. After the disc was deployed in the left ventricle, the body of the device was deployed. While the superior edge of the retention disc was deployed inside the ampulla, the inferior edge of the disc was still on the LV aspect (Fig. 2d, e). After deployment of the whole device and before release of the device, proper position of the device with no interference with aortic valve and tricuspid valve were verified. Transesophageal echocardiography shows no significant valve regurgitation and tiny peri-device leak. Then the device was released (Fig. 1a–d). Post-deployment angiograms were obtained to confirm the appropriate device position (Fig. 2f). Transthoracic echocardiography after the procedure showed secure device position and remarkable improvement of LV volume overload with the marked decrease in the LVDd = left ventricular end-diastolic diameterfrom 56 mm to 46 mm (Fig. 3a, b). The peri-device leakdisappeared in three monthsand electrocardiogram did not show any arrhythmia.

Discussion

The pmVSD is the most common subtype of VSD. The conduction system is commonly situated postero-inferior to these defects [7]. Traditionally, surgical repair for VSD has been a first-line treatment which has yielded excellent results in Japan and many other countries. Although the outcome of surgical closure is satisfactory, it requires open-heart surgery with cardiopulmonary bypass and is associated with the risks of residual shunt, infection, sternotomy scar, and even death. While the incidence of complete atrioventricular block (CAVB) was described as being lower than 1% of patients after the surgical closure of VSD in contemporary series and it usually appears early after the surgical repair [8], it can occur both as an early and delayed complication in patients treated with transcatheter VSD closure. However, transcatheter closure is obviously less invasive than surgical closure, and it is assumed to reduce perioperative morbidity and mortality.

Transcatheter pmVSD closure is becoming the treatment of choice in selected patients worldwide after the ADO-I was introduced, which is an asymmetrical double-disc device that was first described for the closure of membranous VSD. Because of the high reported incidence of CAVB up to 5.7% [1], the device has not been approved by the US Food and Drug Administration. Many devices have been developed wordwide, based on the device modification to reduce external forces exposed onto the conduction system. According to the accumulation or experience and the development of new devices, the risk of AVB appears to be decreasing to around 0.2% [9].

The risk of AVB is caused by the close vicinity of the atrioventricular conduction bundle that penetrates the central fibrous body located in the postero-inferior border of the pmVSD margin [7]. The majority of CAVB with the ADO-I occurred within the first week, but it also developed more than 1 year after the procedure [10]. Although the mechanism of CAVB is speculated as mechanical compression, inflammatory response, and scar formation, it has not been fully investigated [7]. Oversize of the device can be a risk factor of CAVB because of the proximity of the conduction system to the margins of the defect and younger age at procedure was significantly associated with the occurrence of CAVB [1]. Therefore, in order to avoid these complications, appropriate patient selection, detailed assessment of the defect anatomy and surrounding structures using transthoracic and transesophageal echocardiography before the procedure, and appropriate device size selection is important. When the measurements by echocardiography sometimes differ from that by angiogram, we should take it into account for device size selection.

ADO-I for the closure of pm VSD were reported as a good option in several case series [4–6]. The ADO-I could facilitate more traumatic and inflammatory reaction in the conduction system because of the squeezing effect by the two discs of the device and strong radial force by excessive stiffness. The optimal device, which provides effective closure and low risk of AVB, requires lower radial force against the VSD border and lower clamping force against the ventricular septum, as well as sufficient stability and flow reduction. The ADO-I is available in sizes ranging from 5/4 mm to 16/14 mm. Devices with a diameter up to 8/6 mm have retention disc 4 mm larger than aortic end of the device, while devices larger than 8/6 have retention disc 6 mm larger than that. Depending on the size of the device, they require 5–7 Fr sheath. The design of

ADO-I can minimize the risk of AVB offering effective closure. The absence of right side disc does not cause clamping force against the ventricular septum and minimizes the risk of tricuspid regurgitation, long waist length provides lower radial force and greater stability of the device. From this point of view, we believe that ADO-I can be an effective and safe therapeutic option in selected patients with pm VSD. El Said et al. [6] reported successful closure in 90% without significant complications except temporary AVB in 1 patient, in a series of 21 patients whose weight was 8.6–68 kg. Lee et al. [5] used ADO for VSD and they had no CAVB in their patients.

The inclusion and exclusion criteria of transcatheter pm VSD closure varies in institutions depending on operator's experience and the type of devices used. In our center, the criterion for inclusion were settled as follows: (1) pm VSD with pouch formation, (2) the echocardiographic or clinical evidence of significant left to-right shunt through the VSD, (3) weight >15 kg, (4) defect size <7 mm, (5) aortic valve rim length >5 mm. It was decided based on the fact that it was a newly introduced procedure in Japan and ADO-I was the only available device for this procedure. The exclusion criteria were as follows: (1) VSD associated with other congenital heart disease which can be corrected surgically, (2) VSD with multiple fenestrations, (3) significant atrioventricular and bundle branch block, (4) pulmonary hypertension with right-to-left shunt, (5) significant aortic regurgitation > mild, (6) sepsis, (7) contraindication to antiplatelet therapy. We believe the use of ADO-I is effective and safe in transcatheter pm VSD closure in selected patients.

Conclusion

Use of ADO-I can be a safe and effective option for transcatheter perimembranous VSD closure in Japan where none of the existing devices for VSD closure has been approved. The incidence of CAVB may be less than reported with the original device.

Conflict of interest

No potential conflicts of interest are disclosed.

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