Transcatheter Closure of Perimembranous Ventricular Septal Defect with Immediate Follow-Up

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Abstract

Background : Surgical closure of membranous ventricular septal defect (VSD) is performed by open heart surgery with a small but significant morbidity and mortality. The authors reported here the first group of patients who underwent transcatheter closure of membranous VSD.

Method : Patients who had membranous VSD with significant left to right shunt as shown by echocardiogram were selected for closure. A standard right and left heart catheterization was done under general anesthesia. A complete arteriovenous wire loop from the aorta to the left ventricle and VSD out into right ventricle was formed in order to guide the delivery sheath into the VSD from the right ventricle. The authors used the new Amplatzer™ Membranous VSD Occluder (AGA Medical Corp., USA) to deploy in the VSD position.

Results : There were 4 patients in the present study with age range of 2 to 24 years old (median : 4 years old). Their weight ranged from 10 to 45 kg (median : 12 kg). Qp:Qs ranged from 1.7-2.5 to 1. The device diameter selected was from 6 to 10 mm. All of them were placed without any residual shunt. At one month follow-up all the patients had echocardiographic examination which showed no evidence of residual shunt.

Conclusions : The authors demonstrated that transcatheter closure of membranous VSD could be safely and effectively performed in small children. This device also provided an opportunity for closure of VSD in patients with pulmonary hypertension.

Key word : Transcatheter Therapy, VSD, Cardiac Catheterization

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A membranous ventricular septal defect (VSD) is roughly found in 30 per cent of all congenital heart defects[1,2]. Generally, large a VSD will create a considerable left to right shunt that eventually leads to enlargement of the left ventricle, congestive heart failure and pulmonary artery hypertension. This group of patients are advised to have to VSD closed surgically before 2 years old to prevent long-term pulmonary hypertension[3]. Surgical closure of VSD was traditionally performed by open heart surgery with a small but significant morbidity and mortality (3 to 13%)[4]. There were numerous reports on transcatheter closure of muscular VSD in the past[5-10]. The results were satisfactory in large infants. However, in small infants, significant morbidity and hemodynamic instability were encountered[11]. The new Amplatzer™ Membranous VSD Occluder by AGA Medical Corp Golden Valley, (Minnesota, USA) was developed specifically for closure of membranous VSD[12-14]. The authors reported here first group of patients who underwent transcatheter closure of membranous VSD.

MATERIAL AND METHOD

Indication for transcatheter closure of VSD

The Amplatzer™ Membranous VSD Occluder is a percutaneous, transcatheter occlusion device intended for occlusion of hemodynamically significant membranous ventricular septal defects (VSD) in the membranous ventricular septum[12-14]. Shunts will be considered hemodynamically significant (Qp : Qs > 1.5 : 1)[14], in patients with evidence of left ventricular and/or left atrial enlargement for body surface area as documented by transthoracic echocardiography.

Contraindications

Patients who have subpulmonary or infundibular VSD were excluded since the device may interfere with aortic or atrioventricular valve function. The authors also excluded patients who had active endocarditis or an intra-cardiac mass or vegetation.

Brief device description

The Amplatzer™ Membranous VSD Occluder is a self-expandable, eccentric double disc device made from nitinol wire mesh (Fig. 1). The two discs are connected by a short cylindrical waist which corresponds with the device size. The discs and the waist are filled with polyester patches for thrombogenic effects. An eccentric device has been designed to avoid interference with the aortic and atrioventricular valves. A platinum marker band is sewn to the left sided disc for orientation. The Amplatzer TorqVue™ Delivery System consists of a delivery sheath (7 or 8 French size), dilator, loading device, plastic vise, delivery cable and pusher catheter (Fig. 1).

Procedure

Patients were fully heparinized throughout the procedure so as to keep the ACT greater than 250 msec. Transesophageal echocardiography (TEE) or transthoracic echocardiography were used as an aid in

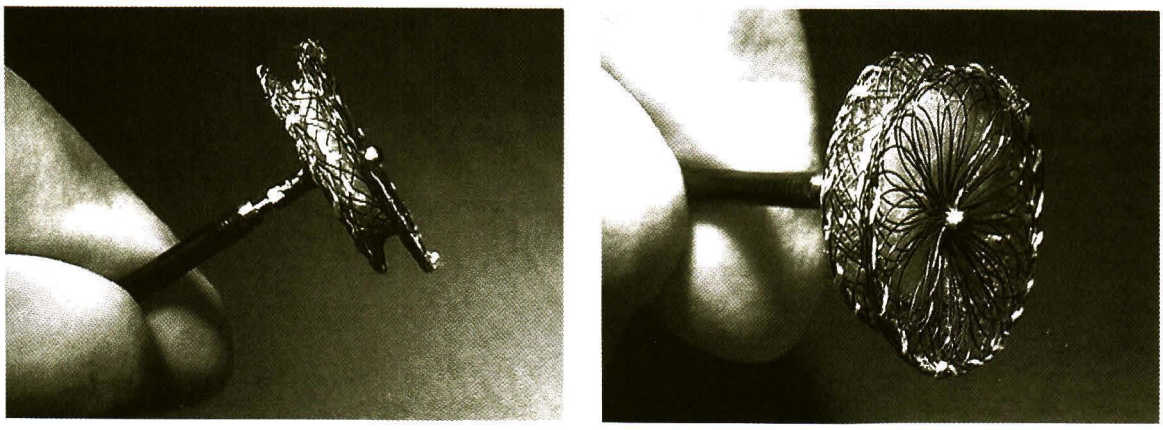

Fig. 1. Amplatzer™ Membranous VSD Occluder was shown with the eccentric device mounted on delivery cable inside the pusher catheter.

placing the Amplatzer™ Membranous VSD Occluder. Prophylactic antibiotic was also given. Femoral vein and femoral artery were punctured. A complete hemodynamic study was performed for the evaluation of oximetry and pressure measurements.

Provide stable arteriovenous loop

Due to the complexity of VSD anatomy the delivery sheath could not be passed into the VSD from the right ventricle. A complete arteriovenous wire loop will be formed in order to guide the delivery sheath into VSD from right ventricle. The authors started by using a right Judkin (JR1 or JR2) coronary catheter advanced into the left ventricle (Fig. 2). Then the catheter was manipulated until it engaged the VSD. An exchange length 0.035" soft J tipped noodle guidewire (AGA Medical Corp.) was introduced into this catheter into the pulmonary artery. The noodle guidewire was snared and exteriorized through the femoral vein. Subsequently, a complete arteriovenous loop was formed (Fig. 3). Then the coronary catheter was advanced retrogradely until it passed the tricuspid valve. The delivery sheath was inserted through the femoral vein. The delivery sheath and dilator were advanced from the femoral vein to the right atrium until they met the coronary catheter (Fig. 4). The system was moved as one unit until the delivery sheath reached the ascending aorta (Kissing catheter technique). Then the coronary catheter was advanced and pushed down upon the tip of the delivery sheath until it reached the left ventricular apex.

Device placement

Device size was selected equally to the VSD size measured from the LV angiogram. The device was screwed on to the tip of the delivery cable with the flat portion of the pusher catheter and device aligned to each other. Without rotation, the system (device, cable and pusher catheter) was advanced until the device reached the tip of the delivery sheath. Under echocardiographic guidance, the sheath was retracted until the left ventricular disc was in contact with the membranous septum. The marker band should be pointing more or less toward the left ventricular apex. The sheath was retraced while maintaining minimal tension on the pusher catheter to deploy the right ventricular disc. The device should properly straddle the interventricular septum (Fig. 5). Left ventricular angiogram and echocardiogram were used to evaluate the residual shunt or valve insufficiency (Fig. 6). The device was released by unscrewing the pin vise in counter clockwise fashion.

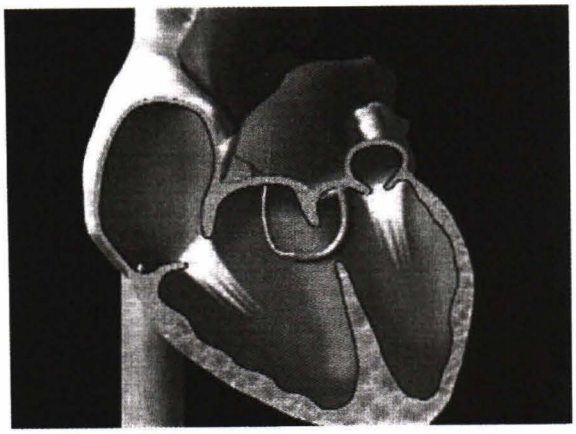

Fig. 2. Right coronary catheter is advanced retrogradely through aortic valve and VSD. Then Amplatzer™ noodle wire is advanced inside the coronary catheter into pulmonary artery.

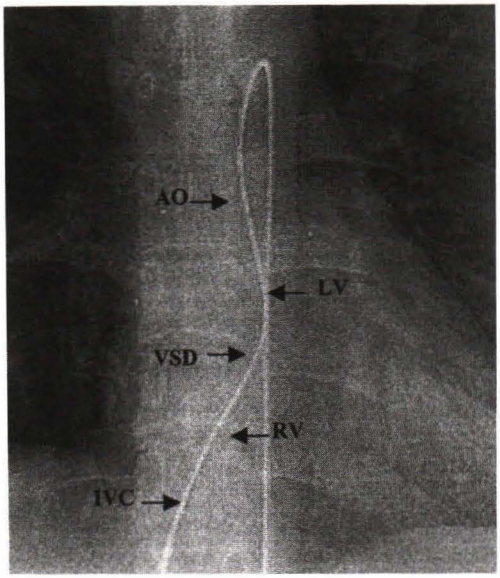

Fig. 3. A complete arteriovenous loop is formed by wire loop from aorta (AO) to left ventricle (LV), Ventricular septal defect (VSD), right ventricle (RV), right atrium and inferior vena cava (IVC)

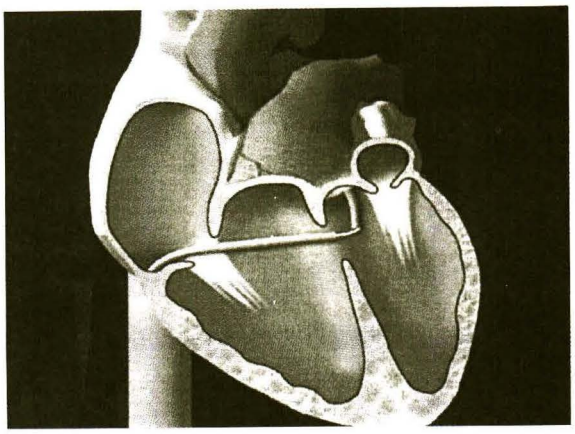

Fig. 4. Amplatzer TorqVue™ sheath is advanced from to inferior vena cava to right atrium and right ventricle and VSD. Tip of coronary catheter is seen from aorta.

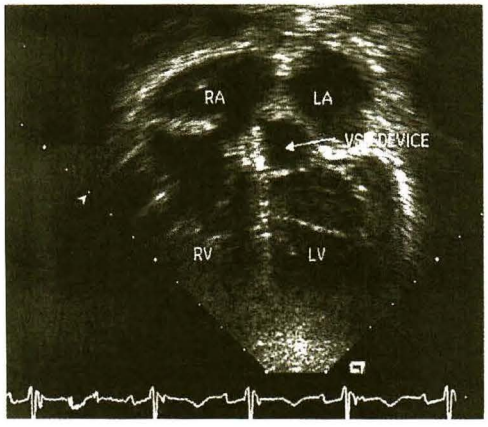

Fig. 6. Echocardiography picture (four chambers view) showing VSD device in position.

RA = right atrium, LA = left atrium,
RV = right ventricle, LV = left ventricle.

Post-implant

Patients should be on appropriate endocarditis prophylaxis and antiplatelet dosage of aspirin for 6 months following device implantation or until the defect has completely closed. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician. Patients will be evaluated and followed at 1, 6, 12 and 24 months.

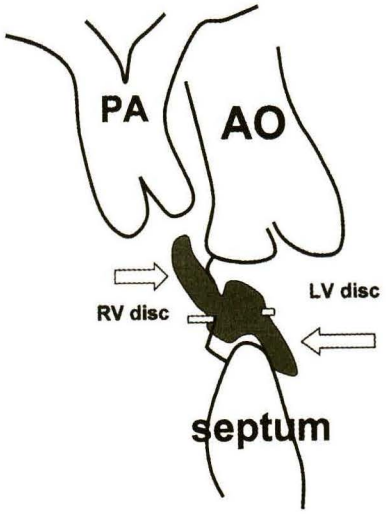

Fig. 5. Schematic figure on VSD device position.

PA = Pulmonary artery, AO = Aorta,
RV = right ventricle, LV = left ventricle,
septum = interventricular septum.

RESULTS

There were 4 patients in the study with an age range of 2 to 24 years old (median : 4 years old). Their weight ranged from 10 to 45 kg (median = 12 kg) The demographic data are shown in Table 1. All of them had a significant left to right shunt from cardiac catheterization (Qp:Qs from 1.7 to 2.5 to 1). They also showed evidence of left ventricular volume overload from echocardiographic examination. The device size selected for placement ranged from 6 to 10 mm. All of them were properly placed without any residual shunt. There was mild aortic regurgitation in one patient (a 2 year old boy). The procedure time varied from 54 to 168 minutes. The fluoroscopic time ranged from 18 to 61 minutes. All patients were discharged the next day with antiplatelet dose of aspirin as home medication.

Immediate follow-up

At one month follow-up, all patients had echocardiographic examination which showed no evidence of residual shunt. One patient who had mild aortic regurgitation showed only a trivial degree of aortic regurgitation.

Table 1. Demographic and VSD measurement in each patient.

Age (yr)	Weight (kg)	VSD size (mm)	Qp:Qs	Device size (mm)	Flu/Proc
3	12	9	2.5	8	18/65
4	17	7	1.7	10	61/168
2	10	8	1.6	6	48/118
22	45	9	1.7	6	23/54

Age (in years), weight (in kg), Qp:Qs = ratio of pulmonary to systemic blood flow, Flu = fluoroscopic time (min), Proc = Procedure time (min).

DISCUSSION

Early attempts of transcatheter closure of VSD were performed during the 1980s[5]. At that time, the devices used were Raskind double umbrella device or Clamp shell device. The type of VSD closed were either apical muscular VSD or post myocardial infarction VSD[6,15,16]. The anatomical proximity of VSD to the aortic valve prevented transcatheter closure of membranous VSD in the late 1990s[12-15]. The newly developed Amplatzer™ Membranous VSD Occluder is a percutaneous, transcatheter occlusion device intended for occlusion of hemodynamically significant membranous ventricular septal defects (VSD). Due to the close proximity of the membranous VSD to the aortic valve, an eccentric device was designed to avoid interference with the aortic and atrioventricular valves (Fig. 5 and 6). Initially, the procedures were performed with significant hemodyanmic instability such as hypotension, dysarrhythmia and blood transfusion[11,16,17]. The new method of providing a stable and complete arteriovenous loop, (Fig. 3) and smaller delivery sheath (7 French) eliminated major complication during the cardiac catheterization procedure[18].

The authors only encountered transient hypotension or dysarrhythmia when the delivery sheath and dilator were pushed from the inferior vena cava across the right atrium, right ventricle into the VSD and aorta. The episode lasted only a few seconds. One must hold both ends of the noodle wire (complete arteriovenous loop) very tight in order to facilitate sheath advancement. Next, by pushing the coronary catheter from the aorta into the left ventricular apex may cause injury to the aortic valve, as the authors suspected in one patient who had mild aortic regurgitation after device placement. Eventually the degree of aortic regurgitation became trivial within one month. The new Amplatzer TorqVue™ Delivery System provided a much smaller sheath size and opportunity to recapture and redeploy the device. The pusher catheter and the platinum marker on the device also helped to prevent rotation of the device and confirmed a proper position of the left ventricular eccentric disc to be away from the aortic valve. All the patients had a very short recovery period in the hospital and provided us a better way to treat high risk patients such as VSD with pulmonary hypertension without effect from cardiopulmonary bypass. Animal study also showed complete endothelized of VSD device surface within 3 to 6 months. Aspirin was continued for 6 months post closure.

SUMMARY

The authors demonstrated the first transcatheter closure of membranous VSD with significant shunt in Thailand. This procedure could be safely and effectively performed with a transcatheter in small children. In the beginning, the authors performed the closure in slightly larger children (> 10 kg). However, this device also provided an opportunity for closure of membranous VSD with a pulmonary hypertension or with slight prolapse of the aortic valve to prevent future aortic regurgitation.

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การปิดรูรั่วที่ผนังกั้นห้องหัวใจด้านล่างโดยการตรวจสวนหัวใจ

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ที่มา : รายงานการรักษากลุ่มผู้ป่วยที่เป็นโรคหัวใจพิการแต่กำเนิดชนิดที่มีรูรั่วระหว่างผนังกั้นห้อง หัวใจด้านล่างแบบ membranous ventricular septal defect (VSD) โดยการปิดรูด้วยการสวนหัวใจแทนการ ผ่าตัด

ผู้ป่วย : ได้คัดเลือกผู้ป่วยที่มี VSD ขนาดใหญ่ จากการตรวจ echocardiogram โดยผู้ป่วยจะได้รับการตรวจสวนหัวใจและใช้อุปกรณ์ Amplatzer™ Membranous VSD Occluder (AGA Medical Corp.) เป็นอุปกรณ์สำหรับปิดรูรั่ว

ผลการรักษา : มีผู้ป่วย 4 ราย อายุตั้งแต่ 2 ถึง 24 ปี และน้ำหนักตั้งแต่ 10 ถึง 45 กก มีค่า Qp:Qs ตั้งแต่ 1.7 ถึง 2.5 ต่อ 1 ขนาดอุปกรณ์ที่ใส่ตั้งแต่ 6 ถึง 10 มม สามารถปิดรูรั่วได้หมดทุกรายทันที ติดตามการรักษาทุกราย โดยใช้ echocardiogram ที่ระยะเวลา 1 เดือน พบว่า สามารถปิดรูรั่วได้ทั้งหมด โดยไม่มีผลแทรกซ้อน

สรุป : ได้ทำการปิดรู membranous VSD ด้วยวิธีการตรวจสวนหัวใจแทนการผ่าตัดในผู้ป่วย 4 ราย พบว่าได้ผลดี และสามารถนำอุปกรณ์นี้มาใช้ในผู้ป่วย VSD ที่มีอัตราเสี่ยงสูงในการผ่าตัด

คำสำคัญ : การปิดรูรั่วระหว่างผนังหัวใจด้านล่าง, การตรวจสวนหัวใจ, Amplatzer Septal Occluder

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