

# Surgical Management for Complications during Closure of Atrial Septal Defect with Amplatzer Device

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**Background:** Transcatheter closure of secundum type atrial septal defect (ASD) has become a standard procedure in most medical centers. Although the procedure is invasive and has a shorter recovery duration and a lower complication rate compared with surgery, it is not risk-free. In this retrospective chart review case series, we report our experience of management of complications after placement of an ASD occluder.

**Methods:** Between January 2000 and December 2010, a total of 508 patients in our hospital underwent closure of secundum type ASD using an Amplatzer septal occluder (ASO). Six of the patients (1.2%) had device embolization or migration warranting surgical retrieval and repair.

**Results:** All the devices were removed and the defects were repaired successfully without any mortality.

**Conclusions:** Surgical intervention for complications of ASO placement in patients who underwent closure of secundum type ASD is safe and effective.

**Key Words:** Amplatzer occluder • Atrial septal defect • Surgical management

## INTRODUCTION

Atrial septal defect (ASD) is one of the most common congenital heart defects, and the prevalence of secundum type ASD in Taiwan's population is about 3.2 per 1,000 live births.<sup>1</sup> Cardiac surgery for closure of ASD has been practiced for more than 50 years.<sup>2</sup> However, since the first transcatheter closure of ASD, which was conducted in 1976,<sup>3</sup> there has been a trend to favor this technique over surgery due to its minimal invasiveness, lower morbidity, lower mortality, as well as shorter hospital stay and recovery, and it is now considered the treatment of choice.<sup>4,5</sup> Several reports have compared

the results and complications of the two methods (device vs. surgical closure) and found identical closure rates.<sup>6</sup>

Although previous case reports already demonstrated complications of transcatheter closure requiring surgical extraction,<sup>7-11</sup> we planned to evaluate the results and safety of surgical retrieval of embolized or migrated ASD closure devices in a Taiwanese cohort of ASD patients.

## MATERIALS AND METHODS

In total, 508 patients received transcatheter occlusion of secundum type ASD with an Amplatzer septal occluder (ASO) (St. Jude Medical, Inc. St. Paul, MN, USA) in our hospital between October 2001 and December 2010. The standard catheter procedure has been described previously.<sup>12</sup> Six patients (1.2%) had device-related complications and received surgical intervention. In this group, a total of 8 devices were implanted

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during 7 transcatheter procedures (Table 1). Four of the eight devices were embolized and two of them migrated which led to residual shunt. All of the patients had been diagnosed with secundum type ASD before the catheter procedure and one patient was suspected of having a large inferior sinus venous type ASD after surgical repair (patient 4). The mean age of the patients was 27 years. The size of ASD ranged from 14.9 to 24.1mm (measured by angiography, and only embolized or migrated ASD was calculated) with an average of  $20.3 \pm 2.7$  mm. The mean pre-operative pulmonary-systemic flow ratio (Qp/Qs) was 3.6 (range: 1.77 to 6). All patients received full sternotomy except one patient (patient 5) who received partial sternotomy for cosmetic consideration (Table 2). Standard cardiopulmonary bypass techniques were used in all patients (bicaval cannulation, antegrade cardioplegia and moderate hypothermia to 32 °C) and the ASDs were approached through the right atrium. Direct closure with Prolene sutures was performed in three patients, while the others were repaired with autologous pericardium patches.

**RESULTS**

Four of our patients suffered from device embolization. Two of the devices were embolized into the left atrium, one in the right ventricle and another on the tricuspid annulus. Three of the patients had undergone surgery within 24 hours (patients 2, 4, and 5) after their transcatheter procedure due to device embolization noted during or immediately after the procedure. In patient 4, pre-cath echocardiography revealed secundum type ASD with two defects (5.8 mm and 14.1 mm). Two devices were implanted during the catheter procedure (device size: 8 mm and 30 mm). The 8 mm device was deployed successfully but the large one immediately migrated into the left atrium. Surgical retrieval with ASD repair was then performed. An inferior sinus venous type ASD and a small patent foramen ovale (PFO) were identified during operation. Both occluders were removed. The PFO was closed directly, and the ASD was repaired with an autologous pericardium patch.

A delayed device embolization was noted in one patient (patient 6) who presented with sudden onset of shortness of breath and chest tightness 8 days after ASO

**Table 1.** Characteristics of patients

	Gender	Age (yrs)	Height (cm)	Weight (kg)	Implantation time	PA pressure (S/D/M) (mmHg)	ASD type	ASD TTE (mm)	ASD size ICE (mm)	ASD stretched size cine (mm)	ASD stretched size ICE (mm)	Sizing plate (mm)	Device size (mm)	Qp:Qs	Device type	Procedure time (min)	Fluorotime (min)
1	M	43	165	56	12/2005	39/12/24	Secundum	23 × 26	24.4/25.2	25.3	28.3	28	28	3.29	Amplatzer	82	19.8
2	M	3	86.5	10.2	9/2006	15/9/12	secundum	13.1 × 22.5	13.1/22.5 (by TEE)	21.8	22	22	20 → 22	5.66	Amplatzer	55	11
3	M	53	168	77	6/2006	29/13/19	Secundum (multiple fenestrated)	Fenestrated ASD largest 5 mm	6.8/8.5	15.4	14.5	14	16	1.77	Amplatzer	105	33.6
4	M	10	146.5	41	3/2007 12/2008	35/20/27	Secundum inferior sinus venous type	5.8; 14.1	10.5; 15.2 8.3 × 6.4 21.6 × 24.6	29.9 7.3 27.5	28.2 9.5 28.3	30 7 NA	30 8 30	2.2 2.4	Amplatzer Amplatzer	104 250	37.1 69.3
5	F	14	160	48	8/2009	35/17/26	Secundum	19.4	22.3/21.8	36.00	34	34	34	4.2	Amplatzer	90	18.2
6	F	41	154	66	8/2010	48/19/33	Secundum	24	21.6/26.9	N/A	N/A	NA	34	6	Amplatzer	70	29.8
	mean	27.3												3.65		108 ± 60	31.3 ± 17.7

ASD, atrial septal defect; ICE, intracardiac echo; PA pressure, pulmonary artery pressure; Qp:Qs, pulmonary-systemic flow ratio; S/D/M, systolic/diastolic/mean; TEE, transthoracic echocardiography; TTE, transthoracic echocardiography.

**Table 2.** Surgical data

Patient	1	2	3	4	5	6	Mean ± SD
Indication of operation	Residual ASD, partial dislodge	Embolization to tricuspid annulus	Residual ASD	Embolization to left atrium	Embolization to left atrium	Embolization to right ventricle	
Bypass time (min)	90	72	131	89	66	101	91.5 ± 21.2
Cross clamp time (min)	29	25	62	37	34	61	41.3 ± 14.3
Operation	Direct closure	Direct closure	Autologous pericardial patch	Autologous pericardial patch	Direct closure	Autologous pericardial patch	
Ventilator time (hours)	11	16	17	16	36	16	18.7 ± 8
ICU stay (days)	3	4	3	5	4	3	3.7 ± 0.7
Hospital stay (days)	7	5	5	8	7	10	7 ± 1.7
Complication	Post-cardiotomy syndrome	nil	nil	nil	Post-op hemorrhage	nil	
Follow-up (months)	65	57	50	30	22	10	39 ± 21.6

ASD, atrial septal defect.

had been placed. There was no predisposing factor in this patient such as intense exercise or physical straining. The ASD diameter was 20.6 mm in this patient and the device size was 34 mm. A typical secundum type ASD was noted during operation with sufficient rim surrounding the defect (Figure 1).

Devices in two of our patients (patient 1 and 3) had migrated, which resulted in residual ASD. One of them (patient 3) had multiple fenestrated ASD with atrial septal aneurysm and received ASO device closure (device size, 16 mm). The initial result was good but residual ASD was noted during follow-up 6 months later. The patient received a second transcatheter intervention for closure of residual ASD. However, residual ASD was still noted after the second procedure, and multi-detector computerized tomography (MDCT) showed that the second device did not deployed correctly on the atrial septum but in the left atrium with the rim partially attached on the first ASD device (Figure 2). Surgical repair and removal of the devices were then performed. The other patient (patient 1) received successful device implantation. However, heart murmur was noted 3 weeks after the procedure. The echocardiography disclosed a partially migrated ASO device over the anterior superior aspect of ASD with LA disk pro-

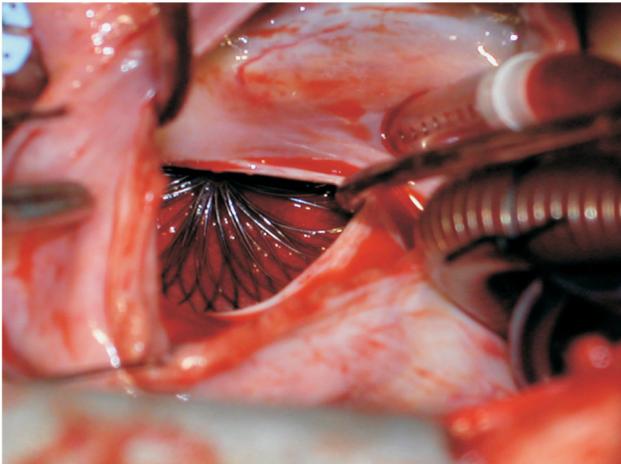
truding to the right atrium and a 5 mm residual ASD was also found. The device was explanted and the atrial septal defect closed by direct suture. The patient also suffered from post-cardiotomy syndrome during follow-up which resolved after medical treatment.

One post-operative hemorrhage was encountered in the patient (patient 5), who received a partial sternotomy. She recovered without any complication after exploratory sternotomy for check bleeding.

There was no mortality, and all patients recovered uneventfully with mean follow-up time of 39 months. No residual ASD was noted on echocardiogram during regular follow-up.

## DISCUSSION

Although the risk of complications following surgical closure of ASD is currently less than 1% in experienced hands,<sup>13</sup> use of the Amplatzer septal occluder has become the more popular approach since its introduction in 1997 for the treatment of secundum type ASD.<sup>14</sup> Many reports showed that the success rate and mortality rate were similar between device closure and surgery groups. However, the complication rate was higher

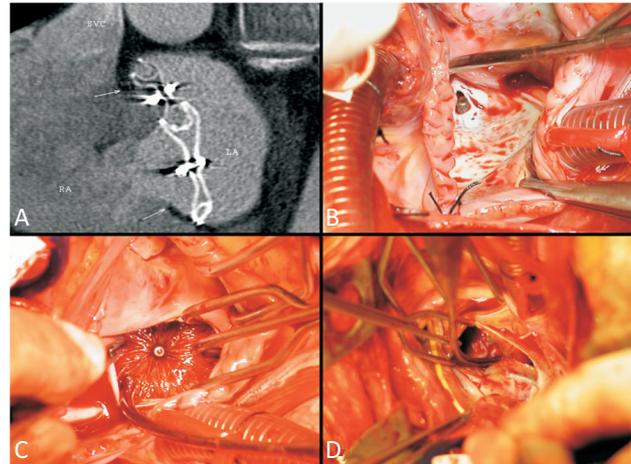


**Figure 1.** The device embolized in the left atrium. A thick rim surrounding this typical secundum type ASD could be seen (view from right atrium).

and the hospital stay was longer in the surgery group.<sup>6</sup> These findings have made the less invasive percutaneous approach more attractive, even though the cost was reported to be higher in the device closure group.<sup>15</sup>

Complications commonly associated with ASD closure device included residual shunt, device malposition or embolization, thrombosis over the vena cava or atrium, erosion and perforation of the heart, and infective endocarditis.<sup>7,8,16</sup> Although the percutaneous intervention technique can handle many of these conditions,<sup>17</sup> others require surgery. Device embolization or erosion could result in catastrophic complications such as left ventricle outflow tract obstruction, cardiac rupture or cardiac tamponade.<sup>8,9,18</sup> Chun reported a case with aorta-to-right atrial fistula 3 months after device implantation.<sup>7</sup> Emergency surgery is usually necessary in these situations. Erosion often occurred in the left atrium and the risk factors related to erosion are ASD size 4 mm larger than the unstretched ASD, and device size greater than 1.5 times the size of the unstretched ASD.

The most frequent complication after ASD device closure is device embolism. According to the literature, rates of embolization ranged from 4% to 20% in different devices and series.<sup>6,9,10</sup> In our group, it was the most common indication for surgery, occurring in 4 of 508 patients (0.8%). An embolized device could induce valve regurgitation, thrombosis formation or ventricle outflow tract obstruction.<sup>18</sup> Several factors related to



**Figure 2.** (A) MDCT scan showed two ASD devices with protrusion into the left atrium and residual shunt. (B) The same heart depicted in (A) showing the multiple fenestrated atrial septum and the second closure device was deployed in the left atrium (view from right atrium). (C) After removing membrane of fossa ovalis. (D) The first ASD device was embedded in hyperplastic intima.

device embolization have been reported and the mostly reported factors were larger ASD (> 20 mm) and device size (> 24 mm), which were also seen in our patients (mean ASD size, 20.3 mm). Undersizing of the device or thin ASD rim would also seem to suggest a high risk of embolization. Mashman et al. reported late device dislodgement related to physical straining and suggested that enough tissue growth and endothelialization provide adequate device fixation.<sup>11</sup> Thus, they suggested avoiding strenuous exercise until 6 months after device implantation.

Device-related thrombus has been reported in many series. Patients could present with stroke or repeated transient ischemic attack, possibly occurring months after device placement occurred.<sup>9,10,19</sup> Clinical risk factors related to thrombus include atrial fibrillation and persistent atrial septal aneurysm. Usually, thrombi resolve spontaneously after anticoagulation therapy with heparin or warfarin. Some thrombi require surgical intervention, although in our cases no patient needed surgery due to thrombus formation. Antiplatelet therapy and routine echocardiography surveillance are suggested to check for thrombus formation.

Rarely, infective endocarditis associated with ASD device occurs, which is probably related to poor endothelialization over the device surface.<sup>16</sup> The infected device should be removed and a full course of antibiotics

according to the bacteria culture should be prescribed. There are currently no guidelines available for prophylactic antibiotics in this group of patients.

Some studies have reported the use of a gooseneck snare or a basket catheter to retrieve embolized devices.<sup>17</sup> Although some success has been reported, most authors have noted that it is difficult to retrieve an embolized or migrated ASD device through the transcatheter approach, and surgery was suggested in most centers.

## CONCLUSIONS

In this 10-year retrospective case series, surgical treatment was required in 1.2% of patients after percutaneous closure of ASD. All devices were successfully removed and the ASDs were repaired without any mortality. Although two complications were encountered, there was no permanent disability after surgical intervention or medical treatment. In spite of the small number of cases, to the best of our knowledge, this is the largest case series in a Taiwanese population. Our findings indicate that surgical intervention to treat complication of device placement for ASD closure is still safe and effective.

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