Predictors of Atrial Septal Defect Occluder Dislodgement

Wei-Chieh LEE,^{1*} MD, Chih-Yuan FANG,^{1*} MD, Chien-Fu HUANG,² MD,
Ying-Jui LIN,² MD, Chiung-Jen WU,¹ MD, and Hsiu-Yu FANG,¹ MD

SUMMARY

The aim of this study was to identify the factors that influence atrial septal occluder dislodgement in adults and children.

From June 2003 to June 2013, a total of 213 patients (115 adults and 98 children) diagnosed with secundum atrial septal defects (ASD) underwent transcatheter closure of their defects with an atrial septal occluder (ASO) in our hospital. The ASO was implanted under transesophageal echocardiography (TEE) guidance. Ten patients suffered from ASO dislodgement, and the other 203 patients comprised the successful group. We compared the preprocedural data related to general demographics, defects, margins, and minor post-implantation complications between the two groups with the goal of identifying the factors that affected ASO dislodgement.

Univariate logistic regression analyses identified a high Qp/Qs value, the Qp/Qs ratio > 3.13, ASO size, ASO size greater than 32 mm, ASO size/BSA ratio > 15.13 and IAS erosion, floppiness or aneurysm formation as factors with significant predictive value. Multivariate analysis revealed that a Qp/Qs ratio > 3.13, and interatrial septum (IAS) erosion, floppiness and aneurysm formation post-implantation were independent predictors of ASO dislodgement ($P = 0.001$ and $P = 0.006$, respectively) in both adults and children.

Percutaneous device closure of ASDs is safe and effective in the current era. The Qp/Qs ratio > 3.13 and IAS erosion, floppiness or aneurysm formation post-implantation might be predictors of ASO dislodgement in adults and children. (Int Heart J 2015; 56: 428-431)

Key words: Transcatheter closure, Atrial septal occluder, ASO dislodgement

Percutaneous device closure of atrial septal defects (ASDs) has emerged as an alternative to traditional surgical closure methods due to its minimal-invasiveness and resultant shorter hospital stays. King and Mills reported the first successful transcatheter closure of an atrial septal defect in 1974.^{1,2)} Lock, *et al* used the modified Rashkind patent ductus arteriosus double umbrella device to close a variety of intracardiac defects, including ASDs and patent foramen ovale. With the introduction of atrial septal occluders (ASO), percutaneous closure has become increasingly popular.³⁾

Current guidelines classify the closure of an ASD with a significant shunt with either percutaneous intervention or surgery as a class IB indication with or without symptoms. Only secundum ASDs should undergo percutaneous closure, and sinus venosus, coronary sinus, and premium ASDs should be repaired surgically. These latter repairs are also class IB indications.^{4,5)} Although the transcatheter closure procedure is safe and effective, it is still associated with some complications such as occluder malpositioning, migration, arrhythmia, air embolism, and aorta perforation.^{6,7)} Among the complications of percutaneous treatment, device dislodgement is one of the most common. Previous studies and current guidelines do not

provide any predictors of ASO dislodgement for either children or adults.^{4,5)}

The aim of our study was to identify the factors that affect ASO dislodgement in both adults and children.

METHODS

Patient collection: Between June 2003 and June 2013, a total of 213 patients were diagnosed with secundum ASD and underwent attempted transcatheter closure with an Amplatzer atrial septal occluder (ASO) at our hospital. The indications for ASD closure were a significant left-to-right shunt and echocardiographic evidence of right heart dilatation with or without paradoxical interventricular septal wall motion. Transcatheter closure of defects using an ASO was performed in 213 patients (115 adults and 98 children).

Procedure and protocol: The entire procedure was performed under general anesthesia. After right heart and left heart diagnostic catheterization, real-time periprocedural transesophageal echocardiography (TEE) was performed by two experienced pediatric cardiologists. Evaluations of the ASDs included as-

From the ¹ Division of Cardiology, Department of Internal Medicine and ² Division of Cardiology, Department of Pediatrics, Chang Gung Memorial Hospital - Kaohsiung Medical Center, Chang Gung University, College of Medicine, Taiwan.

*These authors contributed equally to this work.

Address for correspondence: Hsiu-Yu Fang, MD, Division of Cardiology, Department of Internal Medicine, Chang Gung Memorial Hospital, Kaohsiung 123, Ta Pei Road, Niao Sung District, Kaohsiung City, 83301, Taiwan, R.O.C. E-mail: ast42aiu@hotmail.com

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assessments of the size and position of the defect and its anatomic relationship to the adjacent cardiac structures, including the vena cava, atrioventricular valves, coronary sinus, and all pulmonary veins. The size of the ASD was selected based on the results from the real-time periprocedural TEE without balloon sizing. After the wiggling test and observation, the ASD was implanted through a femoral venous access.

Transthoracic echocardiography, chest radiography (CXR), and electrocardiography (ECG) were performed the day after the procedure. All patients received transthoracic echocardiographic follow-up at 1 month, 3 months, and 6 months followed by yearly visits to assess the results. CXRs were performed at 1 and 6 months to confirm the position of the ASD device during the follow-up period.

Definitions: Floppy IAS and aneurysm formation were defined as the presence of a bulge in the atrial septum that moved back and forth. IAS erosion was defined by the presence of abrasion of tissue of the atrium.

Statistical analyses: The data are expressed as the mean $\pm$ the standard deviation. The factors of ASD size, mean pulmonary arterial pressure, Qp/Qs, gender and ASD rim were analysed using chi-square tests. Receiver operating characteristic (ROC) curves were used to determine the optimal values in terms of sensitivity and specificity. Univariate and multivariate logistic regression analyses were performed to identify the significant predictors of ASD dislodgement. The level of statistical significance was set at $P < 0.05$. All statistical analyses were performed using SPSS 19.0 (SPSS, Inc., Chicago, USA).

RESULTS

Baseline characteristics of the study patients (Table I): A total

of 213 patients underwent transcatheter closure and 10 of these patients experienced ASD dislodgement. There were no statistically significant differences in the baseline or clinical characteristics (including gender, age, mean pulmonary arterial pressure, and incidence of multiple ASDs) between the success and dislodgement groups. The pulmonary to systemic blood flow ratio (Qp/Qs) was significantly higher in the dislodgement group (4.06 ± 1.23 versus 2.43 ± 1.08 , respectively, $P < 0.001$).

Defects and margins (Table I): The ASD size and ASD size/BSA ratio were significantly larger in the dislodgement group than the success group (28.09 ± 9.98 versus 20.22 ± 8.46 , $P = 0.003$; and 21.80 ± 6.55 versus 17.03 ± 8.21 , $P = 0.072$, respectively). The minimum rim length and minimum rim length/BSA ratio were shorter in the dislodgement group, but these differences did not reach statistical significance (7.00 ± 2.88 versus 7.44 ± 4.17 , $P = 0.902$; and 5.32 ± 1.73 versus 6.36 ± 3.41 , $P = 0.394$, respectively).

Aortic rim deficiencies were found in 60% of the patients in the dislodgement group, but this incidence was not significantly different from that in the success group ($P = 0.137$). The percentage of patients in the dislodgement group with inferior vena cava (IVC) rim deficiencies was found to be higher than that in the success group (10% versus 1%, respectively, $P = 0.018$). The incidence of other rim deficiencies was not significantly different between the success group and the dislodgement group. The rate of multiple rim deficiencies was significantly higher in the dislodgement group than the success group (10.0% versus 1.0%, respectively, $P = 0.018$).

Minor complications (Table I): The incidences of IAS erosion, floppiness, and aneurysm formation after ASD implantation were higher in the dislodgement group (40% versus 8.9%, $P = 0.002$). The incidence of arrhythmias, such as atrial fibrillation, premature ventricular contraction (PVC) and supraventricular

Table I. Clinical Characteristics of Patients in Success and Dislodgement Groups

Group	Success (n = 203)	Dislodgement (n = 10)	P
General demographics			
Age	25.46 $\pm$ 21.49	22.35 $\pm$ 15.97	0.568
Male	30.5%	40%	0.528
Qp/Qs	2.43 $\pm$ 1.08	4.06 $\pm$ 1.23	< 0.001
PA mean pressure (mmHg)	18.39 $\pm$ 6.52	18.44 $\pm$ 4.04	0.981
Defect			
Multiple ASDs	11.3%	20%	0.406
ASD size (mm)	20.22 $\pm$ 8.46	28.09 $\pm$ 9.98	0.003
ASD size/BSA	17.03 $\pm$ 8.21	21.80 $\pm$ 6.55	0.072
Margin			
Smallest rim length (mm)	7.44 $\pm$ 4.17	7.00 $\pm$ 2.88	0.902
Smallest rim length/BSA	6.36 $\pm$ 3.41	5.32 $\pm$ 1.73	0.394
Aortic rim deficiency	37.4%	60%	0.137
SVC rim deficiency	0.6%	0%	0.826
IVC rim deficiency	1.0%	10.0%	0.018
MV rim deficiency	0%	0%	-
CS rim deficiency	0%	20%	0.060
RPV rim deficiency	0%	0%	-
Multiple rims deficiency	1.0%	10.0%	0.018
Minor complications			
Eroded and floppy IAS or aneurysm formation	8.9%	40%	0.002
Arrhythmia	4.9%	20%	0.044
Follow-up time (days)	1554.19 $\pm$ 956.71	917.30 $\pm$ 911.63	0.041

*Data are presented as mean $\pm$ SD or number (%) of patients. PA indicates pulmonary artery; ASD, atrial septal defect; ASO, atrial septal occluder; BSA, body surface area; IAS, interatrial septum; SVC: superior vena cava; IVC: inferior vena cava; MV: mitral valve; CS: coronary sinus; and RPV: right pulmonary vein.

tachycardia (SVT), following ASO implantation was significantly higher (20% versus 4.9%, $P = 0.044$) in the dislodgement group.

Receiver operating characteristic (ROC) curves: ROC curves for the Qp/Qs ratio and ASD size/BSA ratio were constructed and revealed that the cut-off points of 3.13 for the Qp/Qs ratio and 15.13 for the ASD size/BSA ratio resulted in the best sensitivities and specificities; the areas under these curves were 0.845 and 0.728 ($P < 0.001$ and $P = 0.015$, respectively).

Predictors of ASO dislodgement (Table II): Univariate logistic regression analyses identified the Qp/Qs value (odds ratio (OR): 2.441 (95% CI: 1.496 – 3.985, $P < 0.001$), Qp/Qs ratio > 3.13 (odds ratio (OR): 34.316 (95% CI: 4.166 – 282.656, $P = 0.001$), ASO size (OR: 1.112 (95% CI: 1.027 – 1.205, $P = 0.009$), ASO size greater than 32 mm (OR: 10.278 (95% CI: 2.716 – 38.888, $P = 0.001$), ASO size/BSA ratio > 15.13 (OR: 8.567 (95% CI: 1.066 – 68.868, $P = 0.043$), and IAS erosion, floppiness or aneurysm formation (OR: 6.852 (95% CI: 1.768 – 26.551, $P = 0.005$) as factors with significant predictive value.

Multivariate logistic regression analysis identified the Qp/Qs ratio > 3.13 (OR: 40.012 (95% CI: 4.473 – 358.842, $P = 0.001$) and IAS erosion, floppiness or aneurysm formation (OR: 10.742 (95% CI: 1.947 – 59.256, $P = 0.006$) as factors with important influence on ASO dislodgement in adults and children.

Reported device migration: The locations of dislodgement included the aortic arch (1), left atrium (2), and right ventricle (7). The patients who exhibited these dislodgements received emergency surgery for ASD closure and device migration.

DISCUSSION

Asia has the highest reported incidence of congenital heart disease (CHD) per 1000 births (9.3 per 1000 live births). ASD has been found to be the second most common CHD,

and its birth prevalence is approximately 1.5 per 1000 live births.⁸⁾ If ASD patients have an ASD with long-term left-to-right shunting, ASD can induce symptoms, such as right heart enlargement, and progress to heart failure (HF) and increase the incidence of atrial arrhythmia.⁴⁾ Approximately 14% of patients with atrial septal defects exhibit rapid progression, which can lead to shunt reversal, disability, and death between 20 and 40 years of age.⁹⁾ The development of transcatheter closure techniques and devices has provided a treatment alternative to ASD closure surgery even in pulmonary valve stenosis and targeted treated pulmonary hypertension patients.^{10,11)} Additionally, transcatheter closure techniques are a preferred choice from a cosmetic perspective, as they greatly diminish the morbidity associated with open-heart surgery, reduce hospital stay, and allow patients to return to their normal daily activities sooner.

Complications of percutaneous transcatheter ASD closure: Although the complication rate following percutaneous transcatheter ASD closure is low,¹²⁾ the most frequent serious complications as reported in a recent analysis of the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database are device dislodgement and cardiac perforation, erosion, or rupture (PERs).¹³⁾ The rate of ASO dislodgement was reported to be about 2-5.5% in previous studies.¹⁴⁾ The common reasons for ASO dislodgement are the use of an undersized ASD device, greater defect size, left atrium too small to accommodate the device, an inadequate or floppy rim, device mobility post-implantation, and operator-related technical issues.¹⁵⁾

The majority of ASO dislodgements occurred within 24 hours of the procedure. Durmus, *et al* stated that the cause of acute device migration is potentially acute changes in intracardiac pressure due to physical strain or a sudden increase in the afterload of the left heart.¹⁶⁾ This hypothesis suggests that a higher QP/QS ratio is strongly related to ASO dislodgement.¹⁷⁾ Subacute or late dislodgement within several days of the procedure are thought to be associated to a large extent with aortic rim erosion or a floppy septum.¹⁸⁾

Table II. Univariate Analysis and Multivariate Cox Regression Analysis for Dislodgement

Variable	Univariate analysis			Multivariate analysis		
	Odd ratio	95% CI	P	Odd ratio	95% CI	P
Defect						
Qp/Qs	2.441	1.496 ~ 3.985	< 0.001			
Qp/Qs > 3.13	34.316	4.166 ~ 282.656	0.001	40.012	4.473 ~ 358.842	0.001
PA mean pressure	1.001	0.903 ~ 1.110	0.981			
Multiple ASD	1.957	0.102 ~ 2.555	0.414			
ASO size (mm)	1.112	1.027 ~ 1.205	0.009			
ASO size > 32 mm	10.278	2.716 ~ 38.888	0.001			
ASO size/BSA	1.052	0.988 ~ 1.120	0.116			
ASO size/BSA > 15.13	8.567	1.066 ~ 68.868	0.043			
Margin						
Smallest rim length	0.989	0.811 ~ 1.167	0.902			
Rim length/BSA	0.893	0.689 ~ 1.155	0.388			
Aortic rim deficiency	2.507	0.685 ~ 9.167	0.165			
IVC rim deficiency	11.17	0.924 ~ 134.90	0.058			
Multiple rim deficiency	11.17	0.924 ~ 134.90	0.058			
Minor complications						
Eroded and floppy IAS or aneurysm formation	6.852	1.768 ~ 26.551	0.005	10.742	1.947 ~ 59.256	0.006
Arrhythmia	4.825	0.904 ~ 25.755	0.066			

PA indicates pulmonary artery; ASD, atrial septal defect; ASO, atrial septal occluder; BSA, body surface area, IAS, interatrial septum; and IVC: inferior vena cava.

Predictors of ASO dislodgement: The current guidelines do not mention any parameters that can predict ASO dislodgement during the performance of transcatheter closure for ASD.^{4,5)} Previously reported predictors include ASD size, pulmonary arterial pressure, a high QP/QS ratio, a septal rim length < 5 mm, a superior posterior rim or aortic rim deficiency, and a floppy or eroded IAS or aneurysm formation during ASO implantation.^{19,20)}

In our study, we excluded some patients with thin and inadequate rims or extremely large ASDs. Neither pulmonary arterial pressure nor multiple ASDs were found to be risk factors for ASO dislodgement. The ASD size was larger in the dislodgement group, but this difference did not reach a significant difference. Although the incidence of arrhythmia was higher in the dislodgement group, this difference also failed to attain significant predictive value. In our study, we identified two strong predictors that included a QP/QS ratio > 3.13 and an eroded or floppy IAS or aneurysm formation after ASO implantation. High QP/QS ratios might be related to greater changes in intracardiac pressure, which influence device imbalance. Floppy or eroded IAS or the formation of aneurysms following ASO implantation also lead to device dislodgement.

Percutaneous transcatheter ASD closure is not a complication-free technique. Procedural difficulties still exist due to the morphological features of septal defects. New imaging modalities such as real-time 3-dimensional transesophageal echocardiography and intracardiac echocardiography could provide for the high quality imaging for anatomical evaluation including maximum defect size, surrounding rim morphology, and the relationship between device and septal rim.²¹⁾ In the future, new imaging modalities should be used when ASD closure is difficult.

Limitations: Our study was a retrospective report that lacked prospective randomization. Selection bias might have existed during the procedure. Only one ASO was used [Amplatzer ASO (AGA Medical Corporation, MN, USA)] in our hospital. The number of ASO dislodgements was also limited.

Conclusion: A Qp/Qs ratio > 3.13 and eroded or floppy IAS or aneurysm formation post-implantation might be predictors of ASO dislodgement in adults and children.

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