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Transcatheter Closure of Right-to-Left Atrial Shunts Using Amplatzer Septal Occluder

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Abstract

Purpose: We reviewed our experience in the closure of right-to-left atrial shunts using Amplatzer septal occluders. ***Methods:*** This is a retrospective review of 13 patients who underwent transcatheter closure of right-to-left atrial shunts for systemic hypoxaemia, at a median age of 8.0 years (range, 2.1 to 17.5), between April 1998 and March 2005. ***Results:*** The right-to-left shunts were associated with Fontan fenestrations (n=8), pulmonary atresia post right ventricular outflow tract reconstruction (RVOTR) (n=3), and critical pulmonary stenosis post-balloon valvoplasty (n=1) and RVOTR (n=1). The median procedural and fluoroscopic times were 140 minutes (range, 75 to 250) and 23 minutes (range, 13 to 55), respectively. A single occluder, with size ranging from six to 24 mm, was placed in 12 patients, while two (17 mm and 20 mm) occluders were deployed in one. There were no procedural failures or immediate complications. Systemic arterial oxygen saturation increased from 81.0±9.0% to 94.9±2.4% (p=0.008), while the mean right atrial pressure increased slightly from 11.8±3.6 to 13.5±3.5 mmHg (p=0.013) after the procedure. The median follow-up duration was 63 months (range, 7 to 75). One patient developed transient ischaemic attacks within the first week of device implantation. Follow-up echocardiography revealed no leak through the implanted devices, although residual shunts through additional small atrial communications were noted in four patients. ***Conclusion:*** Amplatzer septal occluder effectively eliminates right-to-left atrial shunts with significant improvement in systemic arterial oxygenation. Serial monitoring for systemic venous congestion is, however, warranted.

Key words Amplatzer septal occluder; Atrial shunts

Introduction

Fenestration of the Fontan circuit, which permits right-to-left shunting of blood into the pulmonary venous atrium, has been shown to improve short-term postoperative outcomes by decreasing pleural drainage, length of hospital stay, need for additional postoperative procedures and Fontan failure rate.[1,2] In patients with poorly compliant right ventricles that occur in association with severe right ventricular outflow obstruction, the right-to-left shunt through the atrial septum may likewise benefit by decompressing the systemic venous system and augmenting systemic cardiac output.[3] With gradual resolution of post-operative risk factors that impedes pulmonary blood flow early after Fontan procedure[4] and improvement of right ventricular compliance after relief of right ventricular outflow obstruction and regression of hypertrophic myocardium,[5] spontaneous closure of the fenestration and right-to-left shunt through the atrial septum may occur, respectively. Nonetheless, these residual right-to-left shunts may persist to cause arterial oxygen desaturation, secondary polycythaemia and possibility of paradoxical embolism.

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Amplatzer septal occluder is currently widely used for the occlusion of isolated secundum atrial septal defects, with encouraging short- and intermediate-term results.[6-8] While a number of groups have reported their preliminary experience in using Amplatzer septal occluder to occlude Fontan fenestrations,[9-11] data on the use of this device to occlude atrial septal defects with right-to-left shunts are limited. In the present study, we reviewed our experience in using Amplatzer septal occluders for the closure of right-to-left atrial shunts in patients after the Fontan procedure and in those after relief of right ventricular outflow obstruction for pulmonary atresia or stenosis.

Methods

Patients

Thirteen patients underwent transcatheter occlusion of right-to-left atrial shunts by Amplatzer septal occluder between April 1998 to March 2005. The median age and weight at intervention were 8.0 years (range, 2.1 to 17.5) and 20.5 kg (range, 7.5 to 57.6), respectively. Table 1 summarises their demographic and clinical variables. Eight patients had closure of Fontan fenestrations, while five had closure of atrial septal defects. Of the latter five patients, three had pulmonary atresia with intact ventricular septum and two had critical pulmonary stenosis, all of whom had undergone previous surgical or transcatheter interventions for relief of right ventricular outflow obstruction. Transcatheter occlusions were performed at a median interval of 4.25 years (range, 0.03 to 17.2) after these interventions. The indications were resting hypoxaemia and exercise intolerance.

Diagnostic Catheterisation and Test Occlusion

All cardiac catheterisations were performed under general anaesthesia. The femoral vein was cannulated percutaneously, while a small cannula was inserted into the radial or femoral artery for monitoring of systemic blood pressure. Heparin (100 units/kg) was given once the vascular access was secured. The baseline mean pressure in the baffle or right atrium, systemic blood pressure, arterial oxygen saturation were measured. For post Fontan patients, biplane angiography was performed in the baffle to evaluate the size and location of the fenestration and pulmonary artery anatomy. For patients with pulmonary atresia or critical pulmonary stenosis, angiography was performed in the right atrium and right ventricle, the latter for assessment of right ventricular size and function.

A five- or six-French multi-purpose catheter was used to cross the fenestration or atrial septal defect and exchanged to a balloon wedge catheter to occlude the defect. Haemodynamic measurements were repeated after five minutes of test occlusion. Patients were considered suitable candidates when the systemic arterial pressure remained stable and mean right atrial pressure does not exceed 18 mmHg.[12,13] In the presence of persistent oxygen desaturation despite balloon occlusion, additional sources of right-to-left shunts would be sought.

Device Implantation

Device selection, based on balloon-stretched diameter using a standard sizing balloon, and device implantation were performed as described previously.[8-10] Trans-esophageal echocardiography was used to assist in sizing of the defect and subsequent deployment of device. The Amplatzer delivery sheath was positioned through the fenestration or atrial septal defect over a guidewire. The Amplatzer septal occluder was then loaded into the delivery sheath and the distal disk was opened in the pulmonary venous atrium. Under transesophageal echocardiographic guidance, the distal disk was pulled against the baffle or the margins of the atrial septal defect. Deployment of the waist and then the proximal disk into the systemic side of baffle or right atrium was performed under fluoroscopic guidance. After testing the stability of the device by the push-pull maneuver, the device was released. The mean pressure in the baffle or right atrium, systemic blood pressure, arterial oxygen saturation were measured again at five minutes after release of device, followed by angiography in the baffle or right atrium. When occlusion of two of more fenestration sites was deemed necessary, two delivery sheaths would be positioned through the fenestrations with deployment of the smaller occluder followed by the larger one.

Follow-up

Chest X-ray and transthoracic echocardiogram were performed prior to discharge of patients. Daily anti-platelet dose of aspirin (three-five mg/kg/day) was prescribed for six months for those not on warfarin maintenance. Routine follow-up evaluations were scheduled at two weeks, one, three, six and 12 months following device implantation.

Statistical Analysis

Results are expressed as mean±SD or median (range) as appropriate. Comparisons of haemodynamic variables before and after occlusion were performed by paired

Table 1 Demographic, clinical and procedural variables

Patient	Age (yr)	Weight (kg)	Diagnosis	Type of definitive surgery	Interval between definitive surgery and catheter occlusion (yr)	Procedural time (min)	Fluoroscopic time (min)	Device size (mm)	Residual shunt	Pre-occlusion / Latest SaO_2 (%)
1	6.7	14.5	Right isomerism, DORV, PS	Fontan (ECC)	0.30	125	18.7	8	No	60 / 97
2	3.1	14.4	Right isomerism, DORV, PS	Fontan (ECC)	0.53	250	40.6	6	No	84 / 94
3	2.1	7.5	Tricuspid atresia, DOLV	Fontan (atriopulmonary connection)	0.03	125	23.3	10	Trace	72 / 99
4	11.4	23.4	Right isomerism, DILV, Pulmonary atresia	Fontan (ECC)	0.56	140	20.5	9	No	82 / 99
5	8.9	20.5	Right isomerism, DIIV, DOIV, PS	Fontan (ECC)	2.56	118	15.7	6	No	86 / 95
6	17.1	52.2	AV discordant, DORV, PS	Fontan (ECC)	3.92	140	28.3	11	No	91 / 98
7	8.0	15	Mitral atresia, DORV	Fontan (intra-atrial baffle)	4.25	165	54.5	6	Moderate	70 / 86
8	7.5	22.5	Tricuspid atresia, DOLV	Fontan (atriopulmonary connection)	6.58	144	24.4	8	No	81 / 97
9	17.5	51.5	Critical PS	RVOTR	13.36	90	19.8	22	No	86 / 98
10	6.0	17.0	Critical PS	PBPV	6.04	148	31	20	Small	79 / 93
11	17.3	55.0	PAIVS, mild Ebstein anomaly	RVOTR	17.23	185	42	20+17	Moderate	88 / 89
12	17.4	57.6	PAIVS	RVOTR	11.76	75	13.3	24	No	82 / 95
13	5.1	16	PAIVS	RVOTR	4.75	94	14.7	19	No	92 / 100

ECC, extracardiac conduit; DIIV, double-inlet indeterminate ventricle; DOIV, double-outlet indeterminate ventricle; DOLV, double-outlet left ventricle; DORV, double-outlet right ventricle, PAIVS, pulmonary atresia with intact ventricular septum; PBPV, percutaneous balloon pulmonary valvoplasty; PS, pulmonary stenosis; RVOTR, right ventricular outflow tract reconstruction

Student's *t* test. A *p* value of <0.05 was considered statistically significant.

Results

Implantation of the septal occluder was successful in all of the 13 patients. None developed any procedural complications. The median procedural and fluoroscopic times were 140 minutes (range, 75 to 250) and 23 minutes (range, 13 to 55), respectively (Table 1). A single occluder was implanted in 12 patients, while two occluders were implanted in 1 (patient 11). In the latter patient, whom had pulmonary atresia and mild Ebstein's anomaly of the tricuspid valve, three atrial septal defects were identified by transesophageal echocardiography. Two occluders were implanted for the two larger superior defects, while the smallest inferior defect left unoccluded. His oxygen saturation rose from 88% to 96% immediately after the procedure.

All implantations except for one were performed on an elective basis at three months or beyond after the Fontan procedure or relief of right ventricular outflow tract obstruction. One patient (patient 3), however, had persistently low oxygen saturation at around 60-70% after Fontan procedure that entailed early closure of the fenestration on day 10 post-operation. Diagnostic catheterisation performed before occlusion revealed a non-obstructed Fontan circuit and a mean pulmonary arterial pressure on the high side at 18 mmHg. The left pulmonary vasculature appeared slightly hypoplastic. In light of the low systemic oxygen saturation and tolerance to test occlusion, the fenestration was occluded with immediate rise of oxygen saturation to 90%, while the mean pulmonary arterial measured only 16 mmHg.

As a group, the arterial oxygen saturation increased significantly from 81.0±9.0% to 94.9±2.4% (p=0.008) immediately after deployment of the occluder. In addition, a slight elevation in mean right atrial or baffle pressure occurred after the procedure (11.8±3.6 mmHg vs 13.5± 3.5 mmHg, p=0.013). The systemic blood pressure remained stable after the procedure.

The anticoagulation regimen consisted of either long-term warfarin (n=6) or aspirin (n=2) for post-Fontan patients or six months of aspirin (n=5). One patient (patient 9), however, described brief episodes of left upper and lower limb weakness within the first week of the implantation and was suspected to have transient ischaemic attacks. Magnetic resonance imaging and subsequent neurological examinations were normal.

The median follow-up duration since the transcatheter procedure was 63 months (range, 7 to 75). All of the patients were clinically well. The median oxygen saturation in room air at latest follow-up was 97%, (range, 86 to 100). Mild ankle oedema was present in one (patient 12). Enlargement of liver to four cm below the right costal margin occurred in patient 3 who required early closure of fenestration. Repeated cardiac catheterisation at 10 months post-operation revealed a high mean pulmonary arterial pressure at 18 mmHg and an elevated pulmonary vascular resistance of 6.38 Wood units·m^2. Serial echocardiographic assessment did not reveal thrombosis, baffle obstruction and atrioventricular valve regurgitation in any of the patients. Two patients (patients 3 and 10) had a small and two (patients 7 and 11) had a moderate residual right-to-left shunt through separate atrial communications. None had residual leaks through the implanted occluders.

Discussion

Our experience with the use of Amplatzer septal occluder for occluding Fontan fenestrations and atrial septal defects with right-to-left shunting of blood suggests that the procedure is safe and effective for improving systemic oxygenation.

The early postoperative benefits of fenestration in standard-risk patients undergoing Fontan procedure have been demonstrated in a prospective, randomised study reported.[1] As many of the standard-risk patients have good haemodynamics, spontaneous closure of the fenestration occurs in the majority, while transcatheter closure is required only in the minority. We used the Amplatzer septal occluder for all of our patients, although a variety of devices has been reported to be similarly effective.[12,14] Nonetheless, the most important step from the perspective of patient management probably lies in meticulous evaluation of the suitability and timing of fenestration closure. Wrong advice of the closure of right-to-left atrial communications may result in a low-cardiac output syndrome and significant elevation of systemic venous pressure that leads to peripheral oedema, chronic ascites and protein-losing enteropathy. Furthermore, in patients who have undergone Fontan procedure using an extra-cardiac Goretex conduit, it would be extremely difficult to recreate a fenestration by transcatheter means should it be necessary. The importance of initial test occlusion using a balloon wedge catheter cannot therefore be overemphasised. While slightly

different guidelines have been recommended,[12,13,15] in general, suitability for closure is suggested by maintenance of a reasonably normal systemic blood pressure and cardiac output and the absence of significant elevation of systemic venous pressure during test occlusion.

The long-term benefits of fenestration closure in 154 Fontan patients using the Clamshell or Cardioseal device have been reported by Goff and colleagues.[12] While improvement in oxygenation is expected, their study also revealed improved somatic growth and, interestingly, reduced need for anticongestive medication. Cardiac decompensation, as defined by death, Fontan takedown, transplantation or symptoms of heart failure, occurred in 4.5% of their patients. Of noteworthy is that decompensated patients were more likely to have a shorter time interval between Fontan procedure and device implantation. While the optimal timing for fenestration closure remains to be defined, the aforementioned findings tend to support a slightly delayed closure of fenestration, though at the expense of systemic hypoxaemia. Indeed, significant hepatic congestion occurred in patient 3 who underwent early closure of the fenestration for significant oxygen desaturation. Our findings also suggest a significant, albeit small, increase in the systemic venous pressure after occlusion of the fenestration, emphasising the need meticulous monitoring of signs of systemic venous congestion on follow-up.

Experience in transcatheter closure of atrial septal defects with right-to-left shunting of blood, which occurs in association with poorly compliant right ventricles, has been extremely limited.[16] Similar to closure of Fontan fenestration, test occlusion of the defect is essential to determine whether the right ventricle is able to cope with the increased diastolic filling. While we did not encounter any particular difficulties of deployment of the occluder in our patients, Ebeid and coworkers[16] have cautioned on possible interference of occluder placement by the prominent eustachian valve[17] that is a common occurrence in pulmonary atresia with intact ventricular septum. Transesophageal echocardiography hence plays an important role in the monitoring of such placements by ensuring that the two discs are positioned accurately across the atrial septum and that the eustachian valve is not mistaken as the inferior rim. Apart from a prominent eustachian valve, increased right atrial pressure is also typically present. While the right atrial disc of the Amplatzer septal occluder is smaller than that of the left, the increased right atrial pressure does not seem to pose problems on stability of the occluder after deployment.

In summary, transcatheter closure of right-to-left atrial shunts can be accomplished safely and effectively with the Amplatzer septal occluder. As alluded to earlier, the importance of test occlusion prior to permanent implantation of the occluder cannot be overemphasised. Furthermore, serial monitoring for systemic venous congestion is warranted.

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