

Pediatric Interventions

Transcatheter Closure of Fontan Fenestrations Using the Amplatzer Septal Occluder: Initial Experience and Follow-Up

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We have recently used the Amplatzer septal occluder to close Fontan fenestrations. Between June 1998 and December 1999, 13 patients underwent transcatheter occlusion of their Fontan fenestrations. Systemic blood flow decreased significantly without a concomitant decrease in pulmonary blood flow. All residual shunts detectable by oximetry were at sites separate from those into which occlusion devices were implanted. One patient developed severe tricuspid regurgitation following the procedure requiring surgical removal of the device. At the last follow-up, all patients were doing well clinically. There were no shunts detectable through or around the devices by echocardiography. Our experience indicates that the location of the fenestration within the Fontan baffle is critical to avoiding device interference with other intracardiac structures. The Amplatzer septal occluder offers an effective means of transcatheter closure of Fontan baffle fenestrations. Although more experience is needed, our current follow-up data suggest that long-term outcomes will be favorable. *Cathet. Cardiovasc. Intervent.* 51:301–304, 2000. © 2000 Wiley-Liss, Inc.

Key words: cardiac catheterization; congenital heart disease

INTRODUCTION

Fontan baffle fenestration allows right-to-left shunting that enhances cardiac output during the postoperative period, limits systemic venous pressure, and may help to reduce the accumulation of pleural fluid [1,2]. The major indication for baffle fenestration closure is to eliminate the risks of long-term right-to-left shunting. In addition to the use of surgically placed abdominal snares [1,3], a variety of transcatheter approaches to fenestration closure have been described [4–7]. The newly developed Amplatzer septal occluder (AGA Medical, Golden Valley, MN) offers an alternative to other currently available devices. This study describes our initial experience and follow-up evaluation in 13 patients with transcatheter closure of Fontan fenestrations using the Amplatzer septal occluder.

CASE REPORT

Study Protocol

Amplatzer septal occluders were implanted under a protocol approved by the University of Michigan Medi-

cal School institutional review board. Study subjects had previously undergone a lateral tunnel Fontan procedure using Goretex (W.L. Gore & Associates, Flagstaff, AZ) with a 4-mm fenestration created using a standard punch. We reviewed the records of all patients enrolled in this protocol for the purpose of Fontan fenestration occlusion from June 1998 through December 1999. Patient sex, age, weight, and native cardiac anatomy were noted, as well as the time interval between the fenestrated Fontan operation and fenestration occlusion. Cardiac catheterization data included mean pressure and oxygen saturations in the Fontan baffle and aorta before and after fenestration occlusion. Pulmonary vein oxygen saturation was measured before occlusion and was assumed to

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be unchanged after occlusion. The ratio of pulmonary to systemic blood flow before and after fenestration closure was calculated assuming a constant oxygen consumption and neglecting shunting through collateral arteries [3]. Cineangiography within the baffle was performed before and after fenestration occlusion (Fig. 1). Follow-up data included duration of follow-up, pulse oximetry values, chest X-ray determination of device dimensions, and any interval complications. Device dimensions were measured from tip to tip on chest X-rays obtained at 24 hr as compared to subsequent chest X-rays obtained at the most recent follow-up. Echocardiographic data included presence and sites of baffle shunting, presence of thrombus, flow disturbance within the baffle, or device interference with the tricuspid valve or other intracardiac structures. Continuous data are presented as mean \pm standard deviation. Paired *t*-tests were used to compare data before and after fenestration occlusion.

Closure Protocol

Cardiac catheterization for Fontan fenestration closure was performed using general endotracheal anesthesia, systemic heparinization, and antimicrobial prophylaxis using intravenous cefazolin (25 mg/kg). Cineangiography was performed in the Fontan baffle to evaluate pulmonary artery anatomy, fenestration location, and potential additional sites of intracardiac shunting. The fenestration size was determined through the use of a standard sizing balloon. The Amplatzer delivery sheath (6 or 7 Fr) was placed through the fenestration over a guidewire. Under transesophageal echocardiographic and standard biplane fluoroscopic guidance, the device was positioned and released as previously described [8]. Hemodynamic measurements and cineangiography of the Fontan baffle were repeated after occlusion. Patients recovered overnight in the hospital, and two additional doses of intravenous cefazolin (25 mg/kg) were given at 8-hr intervals. A chest X-ray, electrocardiogram, and transthoracic echocardiogram were performed prior to patient discharge. As dictated by the study protocol, aspirin (81 mg/day) was prescribed for 6 months. Routine follow-up evaluation was scheduled at 6 and 12 months following device implantation.

RESULTS

The Amplatzer septal occluder was successfully delivered in all 13 patients attempted with one major complication as described below. Table I summarizes patient and procedure details. Transhepatic access was required in four patients due to femoral vein occlusion ($n = 3$) or congenital interruption of the inferior vena cava ($n = 1$). The patient who received two Amplatzer occluders had three discrete sites of baffle shunting and had devices

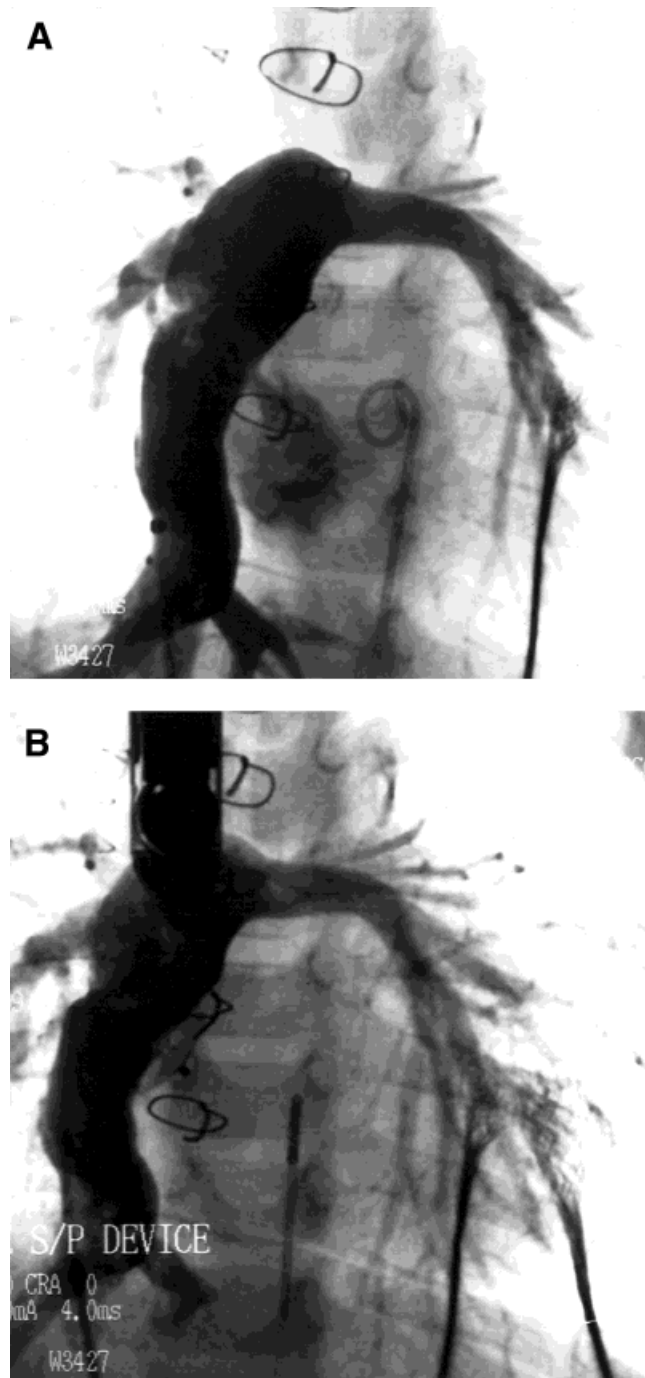


Fig. 1. (A) Contrast injection demonstrates right to left shunting across the Fontan fenestration. (B) Following placement of the Amplatzer septal occluder, no residual shunt is detected.

implanted into the two larger defects with no attempt made to occlude the smallest defect. The hemodynamic data are summarized in Table II. Arterial oxygen saturation and the ratio of pulmonary to systemic blood flow increased significantly while mixed venous saturation

TABLE I. Patient and Procedure Details

	Patient age (years)	Patient weight (kg)	Time since Fontan (years)	Procedure time (hr)	Fluoro time (min)	Access site	Device size	Residual shunt	Additional interventions
	3.8	14.5	2.1	2.2	15.8	Femoral	4 mm	Trace (above fenestration)	
	3.3	11.9	0.7	2.0	17.1	Femoral	4 mm	Trace (above fenestration)	
	19.5	50.6	2.1	3.5	41.2	Transhepatic	4 mm, 5 mm	Mild (above fenestration)	
	3.2	13.2	0.8	3.6	13.1	Transhepatic	4 mm	None	
	2.8	12.5	0.7	2.0	10.8	Femoral	4 mm	Trace	
	3.2	13.6	1.5	3.4	46.4	Transhepatic	4 mm	Trace (above fenestration)	
	2.0	11.5	0.6	2.3	25.5	Femoral	4 mm	None	
	3.0	15.0	0.9	2.0	9.7	Femoral	4 mm	Trace (above fenestration)	
	7.1	22.0	4.8	4.4	25.7	Femoral	7 mm	Trace	
	2.4	14.3	0.8	2.3	12.2	Femoral	4 mm	None	Removal of broken snare system
	3.2	11.5	0.9	3.0	25.7	Transhepatic	4 mm	None	Balloon dilation of LPA stent
	2.1	11.5	0.6	2.5	19.1	Femoral	4 mm	None	Coil occlusion of LSVC
	3.4	15.6	1.7	2.4	19.1	Femoral	4 mm	None	
Median	3.2	13.6	0.9	2.4	19.1				
Mean \pm SD	4.6 \pm 4.8	16.7 \pm 10.9	1.4 \pm 1.2	2.7 \pm 0.8	21.6 \pm 11.3				

TABLE II. Average Hemodynamic Values Before and After Fenestration Closure*

	Before closure	After closure	<i>P</i> value
% systemic saturation	89.3 \pm 4.5	95.6 \pm 2.8	<0.0001
% mixed venous saturation	67.3 \pm 7.9	65.2 \pm 8.7	NS
Mean baffle pressure (mm Hg)	11.6 \pm 2.4	12.7 \pm 1.9	NS
Mean systemic pressure (mm Hg)	57.2 \pm 8.8	59.1 \pm 12.8	NS
Qp:Qs	0.77 \pm 0.12	0.97 \pm 0.06	<0.0001

*NS, not significant; Qp:Qs, ratio of pulmonary to systemic blood flow.

was unchanged. Consequently, a significant decrease in systemic blood flow was calculated ($25\% \pm 16\%$, $P = 0.0005$) without a significant decrease in pulmonary blood flow ($5\% \pm 15\%$, $P = 0.16$). All residual shunts detectable by oximetry were at sites separate from those into which occlusion devices were implanted, typically through intramyocardial channels. Average tip-to-tip dimensions decreased by 13% in the seven patients in whom follow-up X-rays were available for review. The average dimension decreased from 13.9 ± 1.6 mm to 12.1 ± 1.1 mm, $P = 0.009$.

Complications

Three patients had complications from the procedure. In one patient, left-sided atrial fibrin-like strands were

detected by echocardiography, but no clinical sequelae were evident. One patient developed bleeding at the femoral vascular access site during recovery, which was controlled with direct pressure. Blood transfusion was not necessary. One patient developed severe tricuspid regurgitation 2 days following the procedure requiring surgical removal of the device. Upon direct examination, the fenestration site was very close to the valve apparatus, allowing the device to entrap portions of the anterior and septal leaflets. Transesophageal echocardiography during implantation and transthoracic echocardiography 1 day following the procedure had shown no significant tricuspid regurgitation and no interference of the device with the tricuspid valve. The device was removed and a small perforation was successfully repaired. This patient has done well since.

Follow-Up

Follow-up data are summarized in Table III. The average time since the procedure was 10.4 months (range, 1.2–19.5 months). All patients were doing well clinically. There were no shunts detectable through or around the devices by transthoracic echocardiography. There was also no evidence of thrombosis, baffle obstruction, or new atrioventricular valve stenosis or insufficiency. The average room air saturation was 95.3% in the nine patients in whom these data were available at the last follow-up, including the patient who had two devices

TABLE III. Follow-Up Data

Time since procedure (months)	Room air saturation (%)	Echocardiogram
19.5	N/A	No baffle leak/obstruction No baffle
17.3	96	leak/obstruction, mild TR
13.4	89	Third site of right to left shunt
13.3	N/A	No baffle leak/obstruction
14.8	97	No baffle leak/obstruction
13.1	N/A	No baffle leak/obstruction
7.3	98	No baffle leak/obstruction
6.8	93	No baffle leak/obstruction
6.4	91	No baffle leak/obstruction
6.5	98	No baffle leak/obstruction
5.7	98	No baffle leak/obstruction
1.2	98	N/A
N/A	N/A	N/A
Mean \pm SD	10.4 \pm 5.5	95 \pm 3

placed and persistent shunting through a third site. The patient who required surgical device removal and tricuspid valve repair suffered no apparent additional sequelae.

DISCUSSION

Fenestration of the Fontan baffle, although still controversial [9], has been reported to improve mortality and morbidity in patients undergoing Fontan palliation [4]. However, closure of these fenestrations requires an additional surgical or catheter procedure. Our experience with the Amplatzer septal occluder has shown that this device effectively eliminates shunting through occluded communications and yields immediate hemodynamic results that are identical to fenestration occlusion by snare [3]. The Amplatzer device is easy to use, is easily retrieved prior to release, and can be implanted into Fontan fenestrations with acceptable procedure length and radiation time. The profile of the device does not appear to alter blood flow through the baffle significantly. Although the observed foreshortening of the device may result from tissue ingrowth and contraction, whether or not a device positioned within a synthetic baffle undergoes subsequent endothelialization remains unknown. Therefore, while the current protocol required aspirin therapy for 6 months, some patients received additional anticoagulation therapy at the discretion of their regular cardiologist.

Aside from the patient who developed femoral bleeding, the complications encountered early in this patient series likely reflect the normal learning curve inherent to any novel approach using new technology. Our experience emphasizes the importance of adequate heparinization just prior to device delivery to avoid potential thromboembolic events. Our experience also indicates that in addition to careful visualization via fluoroscopy and echocardiography during device implantation, the location of the fenestration within the Fontan baffle is critical to avoiding device interference with other intracardiac structures.

The Amplatzer septal occluder offers an effective means of transcatheter closure of Fontan baffle fenestrations. The device offers advantages in terms of ease of use and retrievability prior to release compared to other currently available devices. Although more experience is needed, our current follow-up data suggest that long-term outcomes will be favorable.

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