SURGICAL MANAGEMENT OF COMPLICATIONS AFTER TRANSCATHETER CLOSURE OF AN ATRIAL SEPTAL DEFECT OR PATENT FORAMEN OVALE

Pascal A. Berdat, MD^a
Tushar Chatterjee, MD^a
Jean-Pierre Pfammatter, MD^b
Stefan Windecker, MD^a
Bernhard Meier, MD^a
Thierry Carrel, MD^a

Objective: During recent years, transcatheter closure has become an alternative to operations for the treatment of atrial septal defects and patent foramen ovale. However, this procedure may be unsuccessful or complicated and requires surgical treatment.

Methods: We retrospectively analyzed the outcomes of patients who needed surgical treatment after failed or complicated transcatheter closure of an atrial septal defect or a patent foramen ovale.

Results: Between April 1994 and March 1999, 124 patients were treated with transcatheter closure of an atrial septal defect or a patent foramen ovale at our institution. We report the results of 10 (8%) patients of this series who required operations after transcatheter closure attempts. In 8 of these 10 patients a significant shunt caused by malposition or dislocation of the device persisted, leading to surgical closure of the defect. In 2 patients injury of the femoral artery at the puncture site required surgical repair. In one patient the device had to be removed surgically from the iliac vein after retraction. One patient died of left ventricular perforation after dislocation of the device and several surgical attempts to close the left ventricular rupture. All other patients recovered well.

Conclusion: An operation was required after transcatheter closure of an atrial septal defect or a patent foramen ovale in 8% of patients. After device complications, the atrial septal defect and the patent foramen ovale can still successfully be closed surgically with good results and low morbidity. However, serious complications like cardiac perforation may have a fatal outcome. Residual shunt, dislocation, or vascular complications are the most frequent problems that require surgical interventions. (J Thorac Cardiovasc Surg 2000;120:1034-9)

During recent years, percutaneous closure of the ostium secundum type of atrial septal defects (ASDs) and a patent foramen ovale (PFO) has become an alternative to surgery. The results of this method, however, have to be compared with those of surgical

closure, which remains the gold standard. Especially the problems encountered after failed transcatheter closure have to be analyzed in detail.

Only by taking into consideration both the results of attempted transcatheter closure and the results of surgical correction after failed or complicated transcatheter closure can the risks of this procedure be fully evaluated. We report early and late outcome of 10 (8%) of 124 patients who underwent percutaneous closure of an ASD or PFO and who subsequently required surgical treatment of either cardiac or vascular complications related to the device insertion.

Methods

Patient characteristics. Between April 1994 and March 1999, 124 patients (48 with ASD and 76 with PFO) underwent percutaneous closure of their defect at our institution by use of a

From the Swiss Cardiovascular Center Bern^a and the Division of Pediatric Cardiology,^b University Hospital, Bern, Switzerland.

Received for publication April 28, 2000; revisions requested June 16, 2000; revisions received July 18, 2000; accepted for publication Aug 22, 2000.

Address for reprints: Pascal A. Berdat, MD, Clinic for Cardiovascular Surgery, Swiss Cardiovascular Center Bern, University Hospital, CH-3010 Bern, Switzerland (E-mail: pascal.berdat@insel.ch).

Copyright © 2000 by The American Association for Thoracic Surgery
0022-5223/2000 \$12.00 + 0 12/1/111054

doi:10.1067/mtc.2000.111054

Fig 1. Preoperative echocardiography showing a malpositioned Sideris buttoned device and a significant residual left-to-right shunt through the ASD.

Sideris buttoned device (Custom Medical Devices, Amarillo, Tex) in 52, Amplatzer Septal Occluder (AGA Medical Corp, Golden Valley, Minn) in 28, and others (CardioSEAL Septal Occluder, Nitinol Medical Technology, Inc, Boston, Mass; PFO-Star, Applied Biometrics Inc, Burnsville, Minn; DAS, AngelWings Occluder, Microvent Corp, White-Bear Lake, Minn) in 38 patients. Complications requiring either cardiac or vascular operations occurred in 10 patients. Demographic data are shown in Table I. The mean age at operation was 45 ± 18 years (range, 4-70 years). An ostium secundum ASD was present in 7 patients, with a mean diameter of 25 ± 6 mm (range, 15-31 mm) and a mean left-to-right shunt of 2.8 ± 1.0 (range, 1.3-4.3). A PFO with a grade 3 right-to-left shunt (passage of > 25 bubbles demonstrated by transesophageal echocardiography with bubble contrast enhancement) was present in 3 patients and was diagnosed after a stroke presumed to be caused by paradoxical embolization. The shunt was unchanged in 8 patients (Fig 1) and estimated to be reduced but still significant in 1 patient after an attempt at transcatheter closure. Seven Sideris buttoned devices were used in 6 patients, and 4 Amplatzer devices were used in 3 patients. In the 1 remaining patient, the procedure had to be aborted before a device could be placed because of limb ischemia after initial puncture of the femoral artery.

Patients underwent echocardiography before and the day after the catheter intervention. Echocardiographic results are summarized in Table I. The left ventricular (LV) ejection fraction was normal in all patients ($72 \pm 5\%$; range, 65%-83%). Right ventricular dilation was present in 7 patients, and additional right atrial dilation was present in 6 patients. Pulmonary arterial hypertension was present in 6 patients. Severe mitral regurgitation was present in 1 patient, and mild regurgitation was present in another.

Table I. Baseline data in 10 patients

	Mean $\pm$ SD	Range
Age (y)	45 ± 18	4-70
BSA (m^2)	1.7 ± 0.4	0.7-2
M/F	3:7	
ASD/PFO (patients)	7:3	
ASD diameter (mm)	25 ± 6	15-31
Shunt after device implantation		
Unchanged	7*	
Relevant	1	
Minimal	2	
LV ejection fraction (%)	72 ± 5	65-83
RV dilatation (patients)	7	
RA dilatation (patients)	6	
Pulmonary arterial hypertension (patients)	6†	
Mitral regurgitation (patients)	2	

BSA, Body surface area; RV, right ventricular; RA, right atrial.

*Including 1 patient in whom no device could be placed.

†Data not available in 2 patients.

Follow-up. Data from the latest follow-up period were collected from physical examinations performed recently or telephone interviews, as well as from echocardiography and work done in the vascular laboratory.

Statistics. Data are expressed as absolute values, percentages, or mean $\pm$ SD where appropriate.

Results

Operations. Surgical data are presented in Table II. The mean time interval between implantation of the device and surgical treatment was 155 ± 230 days

Fig 2. A, B, Intraoperative right atrial view with malpositioned Sideris buttoned devices in situ. Picture of the same patient as seen in Fig 1.

(range, 0-748 days). There were 13 operations performed in 10 patients, and the ASD or PFO was surgically closed in 8 patients. Indications for surgical closure of the ASD or PFO were persistent left-to-right shunt caused by malposition or dislocation of the device (7 patients) or preliminary puncture site complication preventing application of a device (1 patient). In 4 patients a polytetrafluoroethylene patch* was needed because the firmly healed device had to be cut out with additional resection of atrial septal tissue. If present, the device was always removed (7 patients, Fig 2). In 1 patient no device had previously been placed interventionally because of injury of the femoral artery and consecutive acute leg ischemia at the start of the procedure. Additionally, mitral valve replacement was done in 1 patient with pre-existent severe mitral regurgitation. In a 70-year-old patient with LV perforation, the operation included closure of the LV and two re-explorations because of persistent bleeding.

In 2 patients iliac or femoral artery injury with consecutive leg ischemia in 1 was treated by reconstruction of the vessel; the second treatment included evacuation of a large retroperitoneal hematoma.

In 1 patient percutaneous retrieval of the dislocated device was successful down to the iliac vein, from where it was extracted surgically to avoid local injury.

In 4 patients surgery had to be performed urgently: in 2 patients as a result of iliac or femoral artery injury, in 1 patient with pericardial tamponade as a result of LV perforation, and in 1 patient with the device stuck in the iliac vein.

Mean operation time was 167 ± 140 minutes (range, 55-540 minutes), cardiopulmonary bypass time was 53 ± 72 minutes (range, 0-256 minutes), and duration of aortic crossclamping was 20 ± 16 minutes (range, 0-44 minutes). Transfusion of blood components was necessary in 5 patients, and the mean number of units of blood components transfused was 5 ± 13 (range, 0-44 units).

Duration of stay in the intensive care unit was 2 ± 1 days (range, 0-3 days), and mean total hospital stay, including hospital stay for interventional and surgical treatment, was 12 ± 5 days (range, 4-20 days). Mean hospital stay for surgical treatment alone was 9 ± 4 days (range, 2-15 days).

Mortality. There was one cardiac-related death. Dislocation of the Sideris device into the ventricle occurred in a 70-year-old patient during percutaneous closure of a 27-mm ASD. Attempts to retrieve the device led to LV perforation with immediate pericardial tamponade. Although emergency surgical intervention was performed, the laceration of the left ventricle could not be treated successfully, and the patient died after 2 re-explorations because of persistent bleeding caused by a coagulation disorder and, ultimately, electromechanical dissociation on the third day.

Morbidity. There was no relevant perioperative or postoperative morbidity after surgical closure of an ASD or vascular intervention. Two patients had transient low cardiac output, with 1 of them having a transient episode of atrial fibrillation. No perioperative cerebral vascular event, bleeding, or recurrent vascular complication occurred. All patients recovered well from surgery and were in functional New York Heart Association class I to II at discharge.

Follow-up. The late outcome of all survivors was good. Mean follow-up time was 698 ± 543 days (range,

*W. L. Gore & Associates, Inc, Flagstaff, Ariz.

Table II. Surgical data in 10 patients

	Mean $\pm$ SD	Range
Time interval to operation (d)	155 $\pm$ 230	0-748
Operation time (min)	167 $\pm$ 140	55-540
CPB time (min)	53 $\pm$ 72	0-256
Aortic crossclamp time (min)	20 $\pm$ 16	0-44
ASD (pc:dc)	4 (2:2)	
ASD pc + MVR	1	
ASD dc + LV suture	1	
ASD total	6	
PFO pc	1	
PFO dc + femoral artery reconstruction + evacuation of retroperitoneal hematoma	1	
PFO total	2	
Iliac vessel reconstruction	1	
Device extraction iliac vein	1	
Transfusion (units)	5 $\pm$ 13	0-44
ICU stay (d)	2 $\pm$ 1	0-3
Surgical hospital stay (d)	9 $\pm$ 4	2-15
Hospital stay (d)	12 $\pm$ 5	4-20

CPB, Cardiopulmonary bypass; pc, patch closure; dc, direct closure; ICU, intensive care unit; MVR, mitral valve replacement.

62-1505 days). No patient died during follow-up. Two patients had mild persistent dyspnea of New York Heart Association class II, and 2 others had palpitations, 1 with mild exercise intolerance. One patient had a painful scar 2 months after vascular surgery and another had dysesthesia of the leg. Oral anticoagulants were used by 4 patients, aspirin by 1, β -blockers by 2, amiodarone by 1, and diuretics by 1. Echocardiographic controls were done in 5 of the 7 surviving patients after cardiac surgery and showed normalization of the cardiac chamber dimensions in 4 patients and normal LV systolic function and no residual shunt in all patients. Vascular examination showed normal peripheral circulation in all 3 patients after vascular procedures. There were no cardiac- or vascular-related readmissions.

Discussion

During recent years, transcatheter closure has become an alternative to an operation for the treatment of ostium secundum ASD and PFO.¹⁻⁴ This new method, however, has to be compared with an operation, which remains the gold standard for the treatment of ASD.

Reports that specifically evaluate the outcome of patients after an operation for failed transcatheter closure are rare.⁵⁻⁹ Therefore more information is needed concerning this subgroup of patients.

Once the indication for closure of an ASD or a PFO is made, the goal of treatment should be a definitive repair. Treatment aims at restitution of normal cardiac anatomy and function, elimination of potential compli-

cations, normalization of life expectancy, and elimination of a requirement for life-long drug therapy. Surgical repair meets these basic requirements and offers reliable and excellent results because closure of an ASD and a PFO can today be done with a mortality rate below 1%¹⁰⁻¹²—in recent series even with zero mortality in any patient group¹³⁻¹⁸—and an overall morbidity rate between 2.5%¹⁰ and 13%,¹¹ with a low probability of residual shunt below 2%.^{11,14} Further surgical improvements of recent years include a less-invasive approach through smaller incisions,¹³⁻¹⁸ improved perfusion techniques, application of fast-track anesthetic protocols, reduction of hospital stay,^{16,17} and reduction of costs. Nevertheless, inherent disadvantages of surgical repair remain, such as the incision, morbidity of cardiopulmonary bypass, post-operative arrhythmias, longer hospital stay, and inability to work for 2 to 4 weeks. From the transcatheter approach, one would expect a very low periprocedural risk, a short learning curve, permanent good results, and a good cost-to-time effectiveness. However, transcatheter procedures are not free of potential complications, such as recurrent cerebral embolism,¹⁹ cardiac perforation leading to tamponade,^{6,15} device malposition or embolization in 4% to 20%,^{8,20-25} residual shunt in up to 30%,^{6,20,26} vascular trauma,^{22,26} thrombus formation on the device,^{6,20} or induced mitral regurgitation.⁸ Considering the present results, an operation after failed or complicated transcatheter closure seems still to be as effective as primary surgical closure because no significant complication occurred after

ASD or PFO closure, and late outcome is excellent. However, one death occurred in this group as a result of LV perforation after failed transcatheter attempts to retrieve a large embolized ASD closure device. Despite emergency operation, the elderly patient died of diffuse persistent bleeding and low cardiac output. Perforation of cardiac or central vascular structures are rarely reported^{6,20,21,26} but mostly require surgical intervention. This case shows that potentially fatal complications may occur during transcatheter closure, which may not be correctable by means of an emergency operation. However, mortality after the transcatheter approach is low, with most authors reporting no mortality in their series.^{3,20,26-28}

In the present report the most frequent indication for surgery (80%) was device malposition or embolism, occurring in 8 (6.5%) of 124 patients. This might be due to the large diameter of 25 ± 6 mm of ASDs in this group. In the literature, device dislocation or embolism is the most frequently reported complication of transcatheter closure, with rates ranging from 4%²² to 21%²⁴ and necessity for surgery in approximately 70% to 100% of those cases.^{4,22-25,27} The dislocation rate is mainly dependent on the device used, with the ASDOS (Øsypka Corporation, Rheinfelden, Germany) and Sideris devices having the highest failure rates.^{6,7,21,23-25} The Amplatzer device shows more promising results. The anatomic features of the ASD (ie, size and quality of the rim) are also of importance.

The second most frequent indication (30%) for an operation in our series was a vascular injury at the puncture site. In the literature complications of the puncture site requiring vascular surgery seem to be rare, with Latson and associates²² reporting 0.5% and Sievert and associates²⁶ reporting 3.4%, which is consistent with our results of 2.4%.

Additional indications for operation were thrombus formation on the device in one patient, recurrent transient ischemic attacks in another patient,¹⁹ and mild mitral regurgitation in a third patient.

All those operations were done without further complications, and late follow-up was excellent, with all patients in functional class I or II. Therefore, our results are comparable with those after primary surgical closure of an ASD or PFO.

In summary, an ASD and PFO can successfully be closed surgically, and the device can be extracted after failed transcatheter closure, with excellent results and low morbidity. However, in cases with serious complications, such as cardiac perforation, there is a fatal risk. Intracardiac dislocation or embolization of the device and complications of the femoral or iliac vessels are the

most frequent problems leading to surgical interventions. Failed or complicated transcatheter closure of an ASD or PFO, occurring in up to 10% of patients, considerably raises the costs of this procedure by lengthening of both intensive care and hospital stay, need for additional operations, and need for blood transfusion.

REFERENCES

- Hijazi ZM, Cao QL, Patel J, Rhodes J. Transcatheter closure of atrial communications using the Amplatzer septal occluder. *J Intervent Cardiol* 1999;12:51-8.
- Chatterjee T, Aeschbacher BC, Meier B. Ischemic attacks and patent foramen ovale: transcatheter closure of patent foramen ovale in adults with cryptogenic systemic embolism. *J Intervent Cardiol* 1999;12:59-64.
- Kaulitz R, Paul T, Hausdorf G. Extending the limits of transcatheter closure of atrial septal defects with the double umbrella device (CardioSEAL). *Heart* 1998;80:54-9.
- Windecker S, Wahl A, Chatterjee T, Garachemani A, Eberli F, Seller C, et al. Percutaneous closure of patent foramen ovale in patients with paradoxical embolism: long-term risk of recurrent thromboembolic events. *Circulation* 2000;101:893-8.
- Horvath KA, Burke RP, Collins JJ Jr, Cohn LH. Surgical treatment of adult atrial septal defect: early and long-term results. *J Am Coll Cardiol* 1992;20:1156-9.
- Bohm J, Bittigau K, Kohler F, Baumann G, Konertz W. Surgical removal of atrial septal defect occlusion system-devices. *Eur J Cardiothorac Surg* 1997;12:869-72.
- Arabia FA, Rosado LJ, Lloyd TR, Sethi GK. Management of complications of Sideris transcatheter devices for atrial septal defect closure. *J Thorac Cardiovasc Surg* 1993;106:886-8.
- Gildein HP, Daebritz S, Geibel A, Sarai K, Vasquez-Jimenez J, Hugel W, et al. Transcatheter closure of atrial septal defects by the "buttoned" device: complications and need for surgical revision. *Pediatr Cardiol* 1997;18:328-31.
- Hekmat K, Mehlhorn U, Rainer de Vivie E. Surgical repair of a large residual atrial septal defect after transcatheter closure. *Ann Thorac Surg* 1997;63:1456-8.
- Galal MO, Wobst A, Halees Z, Hatle L, Schmaltz A, Khougeer F, et al. Perioperative complications following surgical closure of atrial septal defect type II in 232 patients—a baseline study. *Eur Heart J* 1994;15:1381-4.
- Kalmar P, Irrgang E. Cardiac surgery in the Federal Republic of Germany during 1990: a report by the German Society of Thoracic and Cardiovascular Surgery. *Thorac Cardiovasc Surg* 1991;39:167-9.
- Pastorek JS, Allen HD, Davis JT. Current outcomes of surgical closure of secundum atrial septal defect. *Am J Cardiol* 1994;74:75-7.
- Gundry SR, Shattuck OH, Razzouk AJ, del Rio MJ, Sardari FF, Bailey LL. Facile minimally invasive cardiac surgery via ministernotomy. *Ann Thorac Surg* 1998;65:1100-4.
- Daebritz S, Sachweh J, Walter M, Messmer BJ. Closure of atrial septal defects via limited right anterolateral thoracotomy as a minimal invasive approach in female patients. *Eur J Cardiothorac Surg* 1999;15:18-23.
- Byrne JG, Adams DH, Mitchell ME, Cohn LH. Minimally invasive direct access for repair of atrial septal defect in adults. *Am J Cardiol* 1999;84:919-22.

16. Khan JH, McElhinney DB, Reddy VM, Hanley FL. A 5-year experience with surgical repair of atrial septal defect employing limited exposure. *Cardiol Young* 1999;9:572-6.
17. Black MD, Freedom RM. Minimally invasive repair of atrial septal defects. *Ann Thorac Surg* 1998;65:765-7.
18. Barbero-Marcial M, Tanamati C, Jatene MB, Atik E, Jatene AD. Transxiphoid approach without median sternotomy for the repair of atrial septal defects. *Ann Thorac Surg* 1998;65:771-4.
19. Z'Brun A, Dai-Do D, Meier B, Carrel T. Recurrent systemic embolism after transcatheter closure of a patent foramen ovale. *Eur J Cardiothorac Surg* 1997;12:813-4.
20. Rickers C, Hamm C, Stern H, Hofmann T, Franzen O, Schröder R, et al. Percutaneous closure of secundum atrial septal defect with a new self centering device ("angel wings"). *Heart* 1998;80:517-21.
21. Rao PS, Sideris EB, Hausdorf G, Rey C, Lloyd TR, Beekman RH, et al. International experience with secundum atrial septal defect occlusion by the buttoned device. *Am Heart J* 1994;128:1022-35.
22. Latson LA, Benson LN, Hellenbrand WF, Mullins CE, Lock JF. Transcatheter closure of ASD—early results of multi-center trial of the Bard clamshell septal occluder. *Circulation* 1991;84(Suppl):II-44.
23. Lloyd TR, Rao PS, Beekman RH 3rd, Mendelsohn AM, Sideris EB. Atrial septal defect occlusion with the buttoned device (a multi-institutional U.S. trial). *Am J Cardiol* 1994;73:283-91.
24. Worms AM, Rey C, Bourlon F, Losay J, Marcon F, Godart F, et al. French experience in the closure of atrial septal defects of ostium secundum type with the Sideris button occluder. *Arch Mal Coeur Vaiss* 1996;89:509-15.
25. Sideris EB, Leung M, Yoon JH, Chen CR, Lochan R, Worms AM, et al. Occlusion of large atrial septal defects with a centering buttoned device: early clinical experience. *Am Heart J* 1996;131:356-9.
26. Sievert H. Catheter closure of congenital shunts. *Cor Europaeum* 1998;7:59-73.
27. Pfeiffer D, Omran H, Otto J, Lê TP, Neugebauer A, Lüderitz B. Transcatheter closure of interatrial defects using the Babic double-umbrella occluder system. *Thorac Cardiovasc Surg* 1998;46:134-40.
28. Thanopoulos BD, Laskari CV, Tsaousis GS, Zarayelyan A, Vekiou A, Papadopoulos GS. Closure of atrial septal defects with the Amplatzer occlusion device: preliminary results. *J Am Coll Cardiol* 1998;31:1110-6.