

Surgical Management of Complications after Transcatheter Closure of an Atrial Septal Defect or Patent Foramen Ovale

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OBJECTIVE

During recent years percutaneous closure of ostium secundum type of atrial septal defects (ASD) and patent foramen ovale (PFO) has become an alternative to surgery. The results of this method, however, have to be compared to 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 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 Sideris buttoned device (Custom Medical Devices, Amarillo, TX, USA) in 52, AmplatzerTM Septal Occluder (AGA Medical Corp., Golden Valley, MN, USA) in 28, and others (CardioSeal Septal Occluder, Nitinol Medical, Technology Inc., USA; PFO-Star, Applied Biometrics Inc., USA; DAS (Angel-Wings)-Occluder, Microvena Coop., USA) in 38 patients. Complications requiring either open cardiac or vascular surgery occurred in 10 patients.

Demographic data are shown in (table 1). Mean age at operation was 45 ± 18 years (range: 4 - 70 years). An ostium secundum atrial septal defect (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 (Qp/Qs) 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 TEE with bubble contrast enhancement) was present in 3 patients, diagnosed after a stroke presumed to be due to paradoxical embolization. The shunt was unchanged in 8 patients (Fig. 1) and estimated to be reduced but still significant in one after the attempt of transcatheter closure. Seven Sideris Buttoned devices were used in 6 patients, and 4 Amplatzer devices in 3 patients. In the one remaining patient the procedure had to be aborted before a device could be placed, because of limb ischemia following initial puncture of the femoral artery.

Patients underwent echocardiography before and the day after the catheter intervention. Echocardiographic results are summarized in table 1. Left ventricular ejection fraction (LVEF) was normal in all patients (72 ± 5 %, 65-83). Right ventricular (RV) dilation was present in 7 patients, additional right atrial (RA) dilation in 6. Pulmonary arterial hypertension was present in 6 patients. Severe mitral regurgitation was present in one patient and mild regurgitation in another.

Table 1. Baseline data

n=10	mean \pm SD	range
Age [y]	45 \pm 18	4 - 70
BSA [m ²]	1.7 \pm 0.4	0.7 - 2
m:f	3:7	
ASD: PFO [patients]	7:3	
ASD diameter [mm]	25 \pm 6	15 - 31
shunt after device implantation:		
unchanged	7#	
relevant	1	
minimal	2	
LV ejection fraction [%]	72 \pm 5	65 - 83
RV dilatation [patients]	7	
RA dilatation [patients]	6	
Pulmonary arterial hypertension [patients]	6*	
Mitral regurgitation [patients]	2	

* data not available in 2

including one patient, in whom no device could be placed

BSA: body surface area; ASD: atrial septal defect; PFO: patent foramen ovale; LV: left ventricle; RV: right ventricle; RA: right atrium;

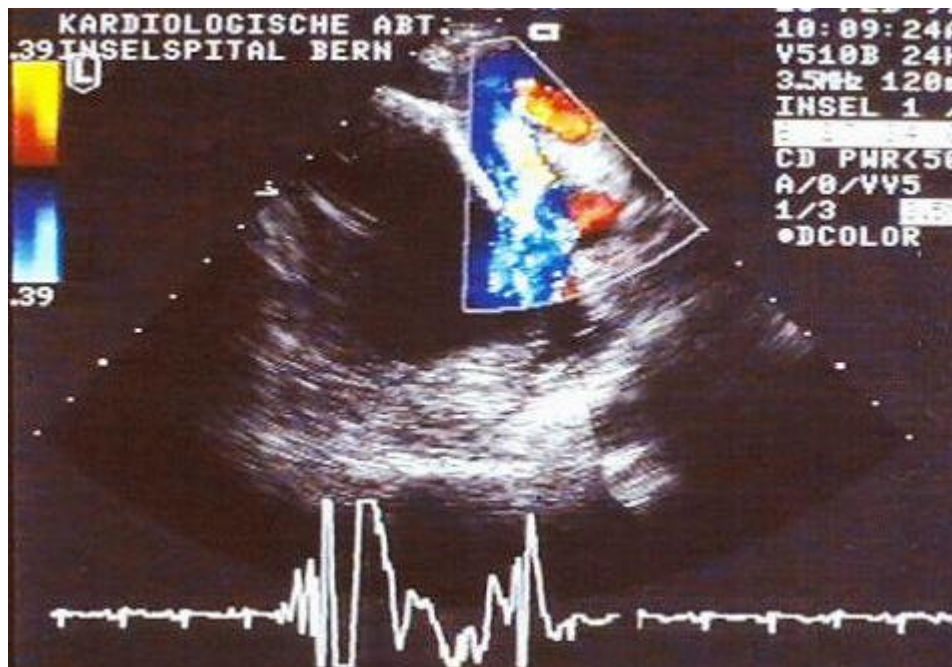


Figure 1

FOLLOW-UP

Data from the latest follow-up were collected from physical examinations performed recently or by telephone interviews as well as from echocardiography and the vascular laboratory.

STATISTICS

Data are expressed as absolute values, percentage or mean \pm standard deviation, where appropriate.

RESULTS

Surgery (Table 2)

The mean time interval between implantation of the device and surgical treatment was 155 \pm 230 (range: 0 - 748) days. There were 13 operations performed in 10 patients: ASD or PFO was surgically closed in 8 patients. Indications for surgical closure of the ASD or PFO were persistent left-to-right shunt due to malposition or dislocation of the device (7 patients) or preliminary puncture sight complication preventing application of a device (one patient). In 4 patients a Gore-Tex patch (W.L. Gore & Assoc.,

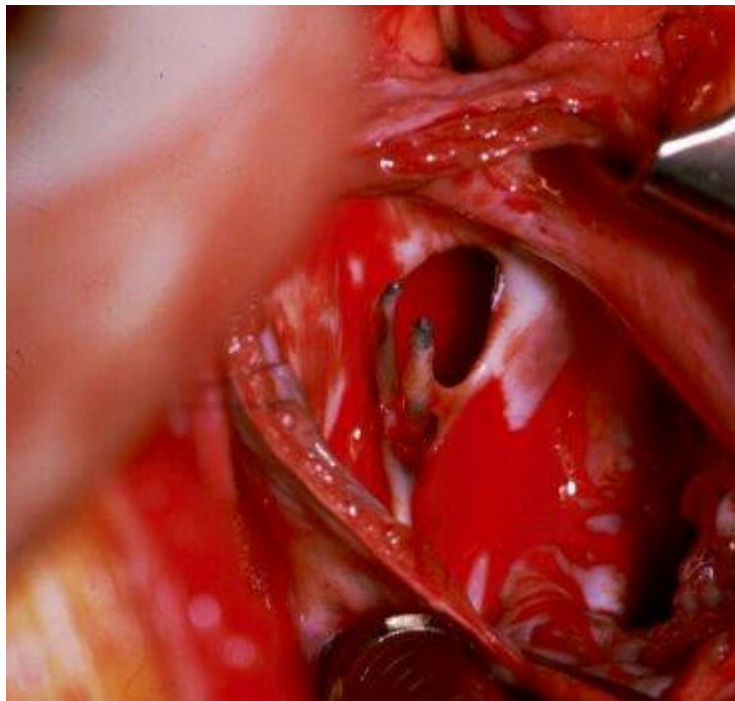
Flagstaff, Arizona) was needed because the firmly healed device had to be cut out with additional resection of atrial septal tissue.

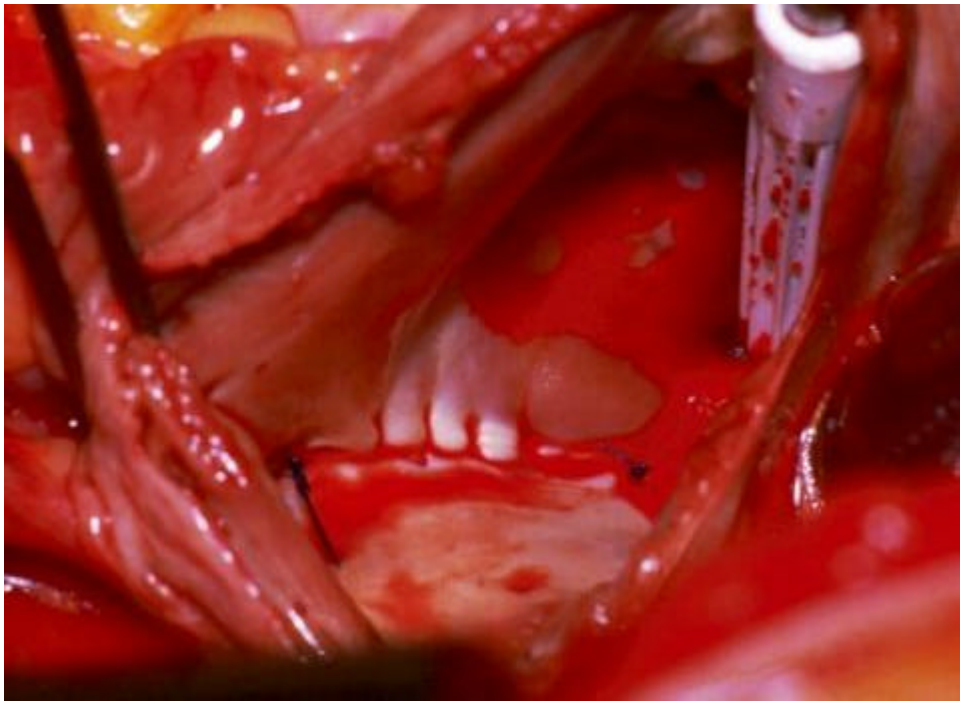
Table 2. Surgical data

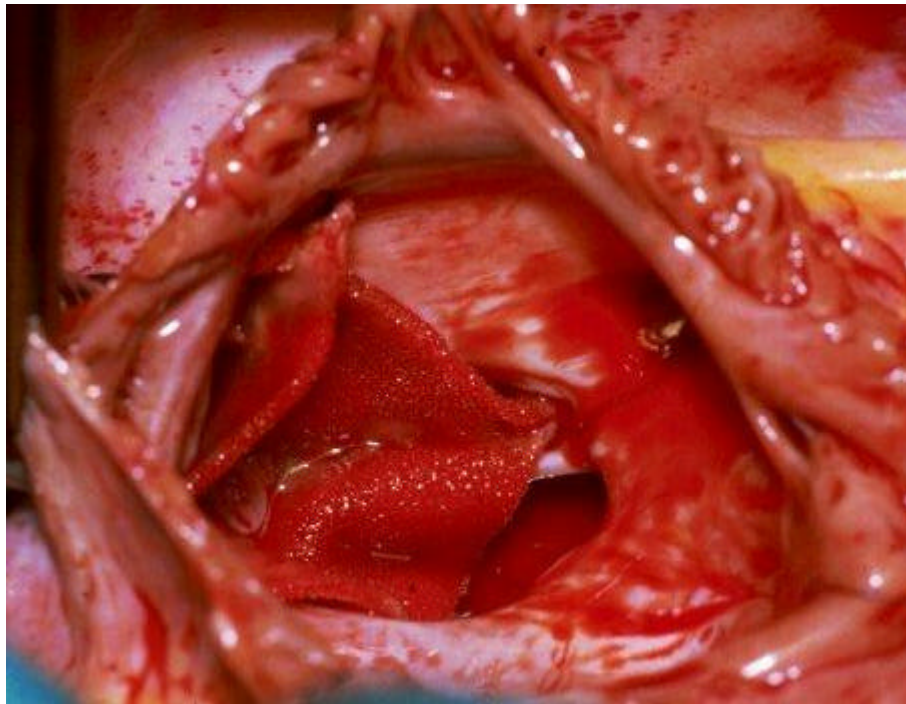
n=10	mean \pm SD	range
Time interval to operation [d]	155 \pm 230	0 - 748
Operation time [min]	167 \pm 140	55 - 540
CPB time [min]	53 \pm 72	0 - 256
Aortic cross clamp time [min]	20 \pm 16	0 - 44
ASD (pc:dc)	4 (2:2)	
ASDpc + MVR	1	
ASDdc + LV suture	1	
ASD total	6	
PFOpc	1	
PFOdc + femoral artery reconstruction + evacuation 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; ICU: intensive care unit; pc: patch closure; dc: direct closure

If present, the device was always removed (7 patients) (Figures). In one 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 one patient with preexistent severe mitral regurgitation. In a 70-year-old patient with LV perforation surgery 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 was treated by reconstruction of the vessel; in the second with evacuation of a large retroperitoneal hematoma.

In one 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 two patients due to iliac or femoral artery injury, in one patient with pericardial tamponade due to LV perforation, and in one patient with the device stuck in the iliac vein.

Mean operation time was 167 ± 140 (range: 55 - 540) min, cardiopulmonary bypass (CPB) time was 53 ± 72 (range: 0 - 256) min, duration of aortic cross clamping (ACC) was 20 ± 16 (range: 0 - 44) min. Transfusion of blood components was necessary in 5 patients, mean number of units of blood components transfused was 5 ± 13 (range: 0 - 44).

Duration of stay in the intensive care unit (ICU) was 2 ± 1 (range: 0 - 3) days, mean total hospital stay, including hospital stay for interventional and surgical treatment, was 12 ± 5 (range: 4 - 20) days. Mean hospital stay for surgical treatment alone was 9 ± 4 (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 an ASD of 27 mm. Attempts to retrieve the device lead to left ventricular perforation with immediate pericardial tamponade. Although emergent surgical intervention was performed, the laceration of the left ventricle could not be treated successfully and the patient died after two re-explorations because of persistent bleeding due to coagulation disorder and ultimately electromechanical dissociation on the third day.

MORBIDITY

There was no relevant peri- or postoperative morbidity following surgical closure of ASD or vascular intervention. Two patients suffered from transient low cardiac output, one of them with 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 NYHA class I-II at discharge.

FOLLOW-UP

The late outcome of all survivors was good. Mean follow-up time was 698 ± 543 (62 - 1505) days. No patient died during follow-up. Two patients complained of mild persistent dyspnea NYHA II, two others complained of palpitations, one of them with mild exercise intolerance. One patient complained of a painful scar two months after vascular surgery and another of dysesthesia of the leg. Oral anticoagulants were used by 4 patients, aspirin by one, beta-blockers by two, amiodarone by one and diuretics by one. Echocardiographic controls were done in 5 of the 7 surviving patients after cardiac surgery and showed normalization of the cardiac chamber dimensions in 4, normal LV systolic function and no residual shunt in all. 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 surgery for the treatment of ostium secundum atrial septal defects (ASD) and patent foramen ovale (PFO) [2 - 5]. This new method, however, has to be compared with surgery, which remains the gold standard for the treatment of ASD.

Reports which specifically evaluate the outcome of patients after surgery for failed transcatheter closure are rare [6 - 10]. Therefore, more information is needed concerning this subgroup of patients.

Once the indication for closure of an ASD or 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 complications, normalization of life expectancy and no requirement for life-long drug therapy. Surgery meets these basic requirements and offers reliable and excellent results, since closure of ASD and PFO can nowadays be done with a mortality rate below 1% [11 - 13] - in recent series even with zero mortality in any patient group [14 - 19] - an overall morbidity rate between 2.5% [11] and 13% [12] with a low probability of residual shunt below 2% [12, 15]. Further surgical improvements of recent years include a less invasive approach through smaller incisions [14 - 19], improved perfusion techniques, application of "fast-track" anesthetic protocols, reduction of hospital stay [17, 18] and costs.

Nevertheless, inherent disadvantages of surgery like the incision, morbidity of cardiopulmonary bypass, postoperative arrhythmias, longer hospital stay, and inability to work for 2 to 4 weeks remain. 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 like recurrent cerebral embolism [1], cardiac perforation leading to tamponade [7, 16], device malposition or embolization in 4 to 20% [7,9,21,22,25-28], residual shunt in

up to 30% [7,20,21], vascular trauma [20,25], thrombus formation on the device [7,21] or induced mitral regurgitation [9].

Considering the present results, surgery following failed or complicated transcatheter closure seems still to be as effective as for primary surgical closure, since no significant complication occurred after ASD or PFO closure and late outcome is excellent. However, one death occurred in this group due to LV perforation following failed transcatheter attempts to retrieve a large embolized ASD closure device. Despite emergency operation the elderly patient died from diffuse persistent bleeding and low cardiac output. Perforation of cardiac or central vascular structures are rarely reported [7,20-22], but mostly require surgical intervention. This case shows, that potentially fatal complications may occur during transcatheter closure, which may not be correctable by emergency surgery. However, mortality after the transcatheter approach is low with most authors reporting no mortality in their series [4,20,21, 23,24].

In the present report, the most frequent indication for surgery (80%) was device malposition or embolism, occurring in 8 of 124 patients (6.5 %). 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% [25] to 21% [27] and necessity for surgery in approximately 70% to 100% of those cases [5,23,25-28].

Dislocation rate is mainly dependent on the device used - the ASDOS and Sideris device having the highest failure rates [7,9,22,26-28]. The Amplatzer device shows more promising results [29]. The anatomical features of the atrial septal defect, i.e. size, quality of the rim are also of importance.

The second most frequent indication (30%) for surgery 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, Latson et al. reporting 0.5% [25] and Sievert et al. 3.4% [20], which is consistent with our results of 2.4%.

Additional indications for surgery were thrombus formation on the device in one patient; recurrent TIA in another one [1], and mild mitral regurgitation in another one.

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 ASD or PFO.

In summary, ASD and PFO can successfully be closed surgically and the device extracted after failed transcatheter closure, with excellent results and low morbidity. But in cases with serious complications like 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 ASD or PFO, occurring in up to 10%, considerably raise the costs of this procedure by lengthening of both intensive care and hospital stay, additional operations, and need for blood transfusion.

ABSTRACT

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

Methods: We retrospectively analyzed the outcome of patients who needed surgical treatment after failed or complicated transcatheter closure of ASD or PFO.

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

Discussion: Surgery was required after transcatheter closure of ASD or PFO in 8% of cases. After device

complications, ASD and PFO 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.

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