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Original article

Management of ostium secundum atrial septal defect in the era of percutaneous trans-catheter device closure: 7-Year experience at a single institution



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ABSTRACT

Objectives: This study aimed to review the single institutional experience of the repair of secundum atrial septal defect (ASD) after the initiation of percutaneous trans-catheter device closure, to confirm the current management strategy and outcomes.

Methods: From August 2005 to December 2012, a total of 1026 (659 females, age 27 ± 21 years) consecutive patients underwent the repair of ASD. Including eight patients who converted to surgical repair, 317 patients (31%) underwent surgical repair and 709 (69%) underwent trans-catheter device closure.

Results: An embolized device into the left atrium was surgically retrieved in one patient soon after trans-catheter device closure without any postoperative complications. The other patient developed left atrium to aorta fistula due to late erosion, and required the removal of implanted device and patch closure of fistula and ASD 3 months after trans-catheter device closure. Whereas serious central nerve system complications occurred in three patients after the surgical repair including a 75-year-old patient with postoperative transient atrial fibrillation who subsequently developed aspiration pneumonia and died; there were no mortalities and no morbidities associated with cranial nerve function after trans-catheter device closure. A number of patients approached through partial sternotomy with limited skin incision have increased per year, and the length of skin incision was 5.1 ± 1.2 cm in pediatric patients weighing less than 15 kg ($n = 40$), 6.9 ± 1.9 cm in the remaining pediatric patients ($n = 91$), and 10.0 ± 2.5 cm in young adult females ($n = 10$).

Conclusion: Percutaneous trans-catheter ASD closure was safely performed under the support of a surgical team. The cosmetic outcome of surgical closure is improving after initiation of partial sternotomy via limited skin incision for the pediatric population and young adult females. Prior to the treatment, the physicians must thoroughly inform patients and families of the advantages and disadvantages of both treatment options.

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Introduction

After a careful clinical trial, percutaneous trans-catheter device closure of the ostium secundum atrial septal defect (ASD) with the Amplatzer Septal Occluder (ASO, St. Jude Medical, St. Paul, MN, USA) has been used in Japan since August 2005 and approved as a

health insurance treatment since March 2006 [1]. The number of treated patients and licensed institutions has been increasing recently [2–4], and most of the treated patients were evaluated concerning trans-catheter ASD closure. Nowadays, the patients who did not meet indications, or who indicated little risk of insufficient treatment and hesitated to receive it, underwent surgical repair.

Although surgical repair of ASD is well known to involve minimal complications, the advantage of trans-catheter device closure is a less invasive approach [5]. Because trans-catheter device closure can be done without a cardiopulmonary bypass, cardioplegic arrest, thoracotomy, and sternotomy, it is completely

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free from open-heart surgery-related complications, such as bleeding, postsurgical inflammatory response syndrome, and central nervous system damage. Moreover, its cosmetic superiority is another attractive advantage for children and adult females. On the contrary, late significant complications could occur after trans-catheter device closure, and outcomes of surgical closure required after trans-catheter device closure are significantly worse, as opposed to that after primary surgical closure [4,6–11]. Therefore, collaboration of cardiac catheter interventionists and surgeons is more essential to treat patients with ASD in the current era.

This study aimed to review the clinical outcomes of repair of ASD after percutaneous trans-catheter device closure was introduced in order to confirm the current management strategy and outcomes.

Patients and methods

Patients

The National Cerebral and Cardiovascular Center Institutional Review Board approved this retrospective study and waived the need to obtain patient consent. From August 2005 to December 2012, a total of 1026 consecutive patients underwent the repair of ASD in our center (Table 1). The diagnosis of ASD was mainly made by transthoracic echocardiography, and the indication for device closure was estimated by transesophageal echocardiography. During the evaluation, patients whose other congenital heart diseases were newly diagnosed, such as partial anomalous pulmonary venous connection, unroofed coronary sinus, or cor triatriatum, were excluded from this study.

Indication for trans-catheter device closure

The indications for percutaneous trans-catheter device closure were well described [1–3]. Briefly, a deficient rim at inferior and/or superior vena cava itself was not a contraindication for deployment; however, it was not indicated if sufficient rim was not presented at one-sixth or greater part of all circumferences.

Technical details of surgical repair

All surgical repairs were performed through median sternotomy. Pediatric patients were operated on by inferior median sternotomy without splitting the presternum through limited skin incision [12,13]. For teenage pediatric patients and adult female patients, whose sternum was completely ossified, the sternal body was divided toward the right side in a reverse L-shape with limited skin incision. Bicaval venous cannulae and ascending aortic cannula were inserted from the same operative field for establishment of cardiopulmonary bypass (CPB). The superior vena cava was snared, but the inferior vena cava was not snared to allow for better inspection of the posterior rim of ASD. Then the aorta was cross-clamped, and antegrade cardioplegia was infused. Electrical ventricular fibrillation was not used, and the defect(s) was closed directly, or with a fresh autopericardial patch. A

prophylactic right atrial cryoablation was added for all adult patients over 20 years old.

Prior to the surgical procedure, autologous blood was not pooled. Cardiopulmonary bypass was primed without a homologous blood transfusion for patients over 9 months old, and a blood transfusion during cardiopulmonary bypass was indicated if the hematocrit level decreased to less than 25% in patients below 9 months old, or decreased to less than 18% in patients over 9 months old.

Study method

This was a retrospective, single-institutional cohort study. From the patients' catheter reports, operative records, and echocardiography reports, the following variables were evaluated: the selected treatments and trends of treated patients, outcomes in patients undergoing percutaneous trans-catheter device closure, outcomes in patients undergoing surgical repair, and a sub-group analysis based on the age of patients undergoing surgical repair.

Sub-group outcomes, such as the prevalence of homologous blood transfusion and the length of the skin incision, were analyzed based on three different generations: Group A consisted of pediatric patients under 20 years old with a body weight of less than 15 kg; Group B, of pediatric patients under 20 years old with a body weight of 15 kg or greater, and Group C, of adult patients over 20 years old.

Results

The trend of treatment selection

Of the 717 patients undergoing percutaneous trans-catheter device closure, eight patients were converted to surgical repair without deployment of devices due to technical difficulties, or devices were once deployed but retrieved for fear of erosion at aortic Valsalva wall. Finally, 709 patients (69%) underwent percutaneous trans-catheter device closure and 317 patients (31%) underwent surgical repair.

The number of treated patients and selected treatment method were altered during the study period (Fig. 1). From 2005 to 2008, both the number of patients undergoing percutaneous trans-catheter device closure and those undergoing surgical closure had increased each year. Since 2008, the number of patients undergoing percutaneous trans-catheter device closure has been stabilized to around 40 cases per year in children and 50 cases in adults because of an increasing number of approved institutions for percutaneous trans-catheter device closure. The number of patients undergoing surgical closure has been also stabilized at around 20 pediatric patients and 10 adult patients per year.

Outcomes in patients undergoing percutaneous trans-catheter device closure

The characteristics of patients undergoing percutaneous trans-catheter device closure are summarized in Table 2. Catheter ablation for atrial fibrillation was previously performed in nine patients. Transluminal pulmonary valvuloplasty for pulmonary stenosis or atresia was performed in 14 patients. As a concomitant procedure, percutaneous device closure or coil embolization of the patent ductus arteriosus was performed in four patients.

Complications after percutaneous trans-catheter ASD closure are summarized in Table 3. There were no mortalities, thromboembolic events, or pericardial effusions. A patient who developed acute mitral regurgitation due to an embolization of the device into the left atrium required emergent removal of the device and mitral valve plasty without any postoperative complications. Another

Table 1
Patient characteristics.

Male:female (n)	367:659
Age [years, mean \pm SD (range)]	26.5 \pm 21.4 (0.5–80)
BW [kg, mean \pm SD (range)]	44.5 \pm 18.5 (4.8–112.6)
Qp/Qs [mean \pm SD (range)]	2.5 \pm 0.9 (0.8–5.6)
Diameter of ASD [mm, mean \pm SD (range)]	18 \pm 8 (2–60)
BW, body weight; Qp/Qs, pulmonary to systemic blood flow ratio; ASD: atrial septal defect.	

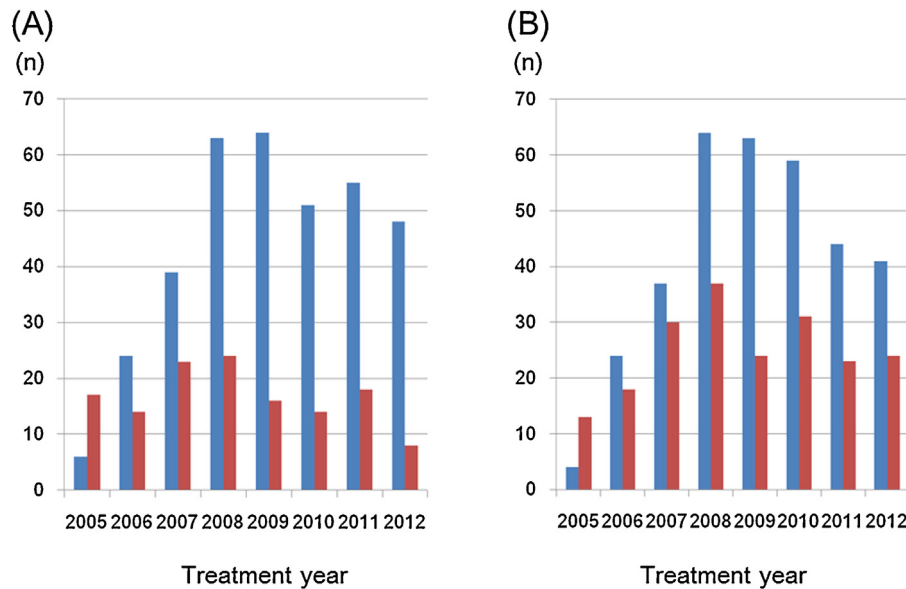


Fig. 1. The number of treated patients and selected treatment in adult patients over 20 years (A), and pediatric patients under 20 years (B). The blue bars indicate trans-catheter device closure, and the red bars indicate surgical closure. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

patient who developed left atrium to aorta fistula due to late erosion of the device required surgical repair 3 months after trans-catheter device closure, also without any complications or sequelae.

Outcomes in patients undergoing surgical repair

The characteristics of patients undergoing surgical closure are summarized in Table 4. Twenty patients (6.2%) and their families preferred surgical repair regardless of an indication of trans-catheter device closure. The diameter of ASD in patients treated with surgery was bigger than trans-catheter device closure (trans-catheter closure vs surgery: 2.3 ± 0.8 vs 2.9 ± 0.9 , $p < 0.001$). Also, estimated Qp/Qs in patients treated with surgery was larger than trans-catheter device closure (trans-catheter closure vs surgery: 15 ± 5 vs 26 ± 10 , $p < 0.001$).

Complications after surgical repair are summarized in Table 5. Seventy-two-year-old males with postoperative transient atrial fibrillation who developed cerebral infarction 20 days after the

operation died due to subsequent aspiration pneumonia. The two remaining patients developed cerebral infarction (a 10-year-old and a 55-year-old female) and were free from recurrent arrhythmia during the perioperative period or congenital or secondary coagulation disorder. Seven patients needed permanent pacemaker implantation for persistent atrial fibrillation despite undergoing the Maze procedure. As minor complications, no patient had residual leakage; four patients needed drainage for pericardial effusion or pleural effusion, and one patient had a wound infection requiring in-hospital treatment.

Outcomes after surgical repair according to generations

Surgical outcomes grouped by three different generations are summarized in Table 6. In Group B, 136 of 139 patients (98%) were free from homologous blood transfusion without preoperative pooling of the patients' own blood.

The number of patients operated on through partial or reverse L-shaped sternotomy with limited skin incision increased by surgical year (Fig. 2). In recent years, most patients under 20 years

Table 2
Characteristics of patients undergoing percutaneous trans-catheter device closure.

Male:female (n)	237:472
Age [years, mean \pm SD (range)]	28 ± 20 (5–80)
Body weight [kg, mean \pm SD (range)]	48 ± 16 (17–113)
Qp/Qs [mean \pm SD (range)]	2.3 ± 0.8 (0.8–5.4)
Diameter of ASD [mm, mean \pm SD (range)]	15 ± 5 (2–31)
Challenging cases (n)	144
Balloon size [mm, mean \pm SD (range)]	18 ± 5 (6–34)
Device size [mm, mean \pm SD (range)]	19 ± 5 (6–34)
Preceding procedure (n)	
Catheter ablation for Afib	9
PTPV for PS or PA	14
Concomitant procedure (n)	
PTPV for PS	3
ADO	2
Coil embolization for PDA	2

ASD, atrial septal defect; Qp/Qs, pulmonary to systemic blood flow ratio; Afib, atrial fibrillation; PTPV, percutaneous transluminal pulmonary valvoplasty; PS, pulmonary stenosis; PA, pulmonary atresia; ADO, Amplatzer ductal occluder; PDA, patent ductus arteriosus.

Table 3
Complications after percutaneous trans-catheter atrial septal defect closure (N=709).

Major complications (n)	
Death	0
Embolization ^b	1
Erosion ^a	1
Advanced AV block	0
Atrial flutter	2
IE	0
Need emergent Op. ^b	1
Minor complications (n)	
Residual leak	0
Transient arrhythmia	3
Migraine	7
Femoral AV fistula (not indicated during surgical repair)	7

AV, atrio-ventricular; IE, infective endocarditis; Op., operation.

^a Left atrium – aorta communication needed surgical repair.

^b The same patient. Acute mitral regurgitation due to the embolization of the device necessitating emergent operation.

Table 4
Characteristics of patients undergoing surgical repair.

Male:female (n)	130:187
Age at Op. [years, mean ± SD]	24 ± 16 (0–76)
Body weight at Op. [kg, mean ± SD]	20 ± 18 (5–88)
Qp/Qs [mean ± SD]	2.9 ± 0.9 (1.5–5.6)
Diameter of ASD [mm, mean ± SD]	26 ± 10 (5–60)
ASO out of indication [n, (%)]	297 (93.7)
Patients' preference [n, (%)]	20 (6.3)

Op., operation; Qp/Qs, pulmonary to systemic blood flow ratio; ASD, atrial septal defect; ASO, Amplatzer septal occluder.

Table 5
Complications after surgical repair (N=317).

Major complications (n)	
Death ^a	1
Cerebral infarction ^a	3
Permanent PMI	7
Atrial tachycardia	3
IE	0
Minor complications (n)	
Residual leak	0
Transient arrhythmia	3
Pericardial effusion	2
Pleural effusion	2
Wound infection	1

PMI, pacemaker implantation; IE, infective endocarditis.
^a The same patient.

could undergo operation with limited skin incision and partial inferior median sternotomy. Of all patients on whom partial median sternotomy was attempted, only one patient with pectus excavatum was converted to full sternotomy due to poor inspection of the operative field. In patients under 20 years, the mean length of the skin incision was 5.1 ± 1.2 cm and the skin incision/height ratio was 0.058 ± 0.02 for patients under 15 kg, and 6.9 ± 1.9 cm with a skin incision/height ratio of 0.054 ± 0.01 for patients over 15 kg.

Table 6
Outcomes after surgical repair by three different generations.

Group	A	B	C
Number of patients	61	139	117
BW (kg)	<15	≥15	
Age (years)	<20	<20	≥20
Homologous blood transfusion [n, (%)]	10 (16.7)	3 (2.2)	26 (22.2)
Limited skin incision [n, (%)]	40 (65.6)	91 (65.5)	10 (8.5)
Length of skin incision (cm, mean ± SD)	5.1 ± 1.2	6.9 ± 1.9	10.0 ± 2.5
Skin incision/height ratio (cm, mean ± SD)	0.06 ± 0.02	0.05 ± 0.01	0.07 ± 0.02

BW, body weight; SD, standard deviation.

Discussion

This study demonstrated the outcomes for repair of ASD in the era of percutaneous device closure. Deployment of the device was tentative or attempted but could not be achieved in the catheter laboratory for eight of 715 patients (1.1%), who successfully underwent a surgical closure. Only two of 709 patients (0.28%) required surgical interventions after trans-catheter device closure, both of which were safely done without any complications. Surgical closure resulted in three postoperative cerebral infarction cases (0.95%), including one mortality (0.32%) case. Recent technical improvement enabled the surgery through limited skin incision in response to current cosmetic demands from patients and the parents, without homologous blood transfusion.

Mortality and serious morbidity rates after both trans-catheter ASD closure with ASO and surgical closure are similarly low [10,11], but what we learn from these large volume studies is that both treatment options may not be completely safe. Although technical complexity does not exist at surgical ASD closure, complications related to open-heart surgery using cardiopulmonary bypass could affect the outcomes. Irregular surface at

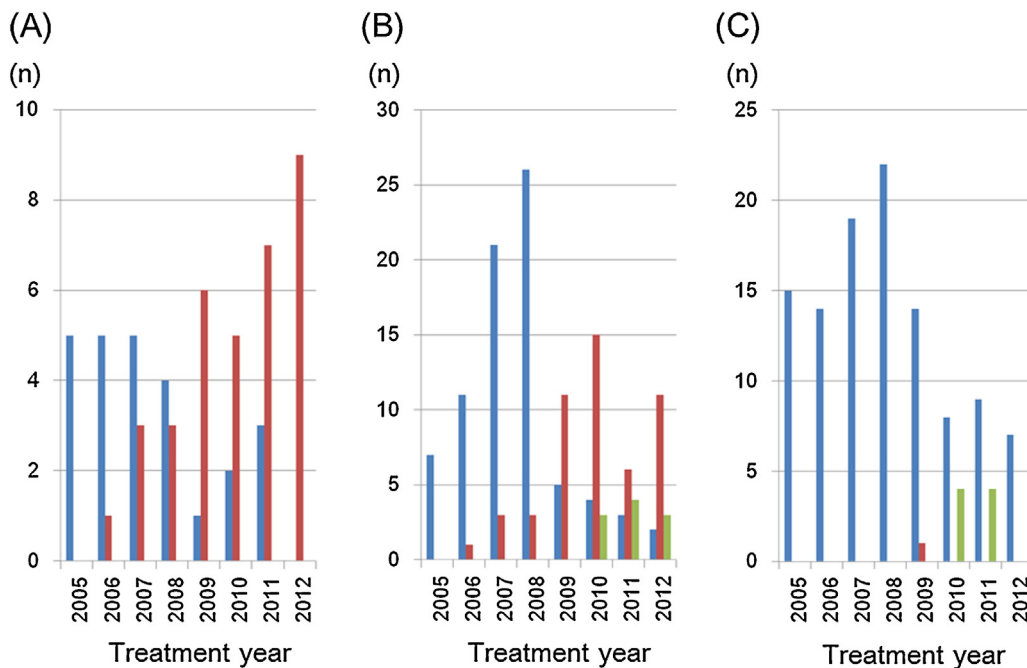


Fig. 2. Surgical approaches in pediatric patients with a body weight of less than 15 kg (A), 15 kg or more (B), and adult patients over 20 years (C). The blue bars indicate full sternotomy, the red bars indicate lower partial sternotomy, and the green bars indicate reverse L-shaped sternotomy. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

surgically treated lesions, hypercoagulability after the surgical stress, or bed rest, may cause thromboembolic events after open-heart surgery. Except one of three patients who developed postoperative cerebral infarction due to transient atrial fibrillation after surgical ASD closure, two remaining patients did not have recurrent arrhythmia and also inherent coagulation disorder such as protein S, C, antithrombin III deficiency, or antiphospholipid syndrome.

On the other hand, our institution did not experience serious complications after trans-catheter device closure, such as erosion of aortic Valsalva, cardiac perforation, or late cardiac tamponade [4,6–9]. These favorable outcomes were provided by the presence of technically sophisticated cardiac catheter interventionists and their careful selection of patients and devices. To avoid the erosion of aortic Valsalva, which was known as the principal cause of death after device closure, the rate of surgical ASD closure is still high in our institution (31%), as opposed to current North American experiences [8,10,11]. For the same reason, retrieval of devices should not be hesitated when unexpected compression of aortic Valsalva was observed even if the device was deployed following careful preoperative evaluation. Indeed, of five patients whose once deployed devices were retrieved in this study cohort, three were for fear of erosion at aortic Valsalva, therefore only one patient in 709 patients developed erosion of aortic Valsalva. Otherwise, the procedure must be performed under the presence of a congenital cardiac surgeon experienced in intra-cardiac anatomy, in order to quickly retrieve the complications surgically [6,7,9].

Technical safety and the possibility of heart surgery with simple congenital cardiac defects in the pediatric population through full sternotomy, partial lower sternotomy, or anterolateral thoracotomy via limited skin incisions have been already reported since the 1980s [12–15]. Although those technical modifications were sometimes introduced as minimally invasive cardiac surgery, congenital heart surgery using the cardiopulmonary bypass was a much more invasive intervention even if it was performed through a small skin incision. For this reason, patients and their families had not paid much attention to the size and location of the skin incision until recently. After the standardization of percutaneous trans-catheter ASD, however, cosmetic demands significantly increased because most patients who spoke to surgeons were disappointed that they expected to undergo catheter treatment but could not, and focused extremely on the length and location of skin incision.

The necessity of homologous blood transfusion is another disadvantage of surgical ASD closure. Including the prevention of viral infections or anaphylactic responses, recent studies revealed the avoidance of perioperative homologous blood transfusion has a merit to reduce postoperative morbidities [16,17]. Although 12% of the patients in this study who underwent surgical ASD closure required a homologous blood transfusion, the prevalence of perioperative homologous blood transfusions decreased to less than 3% if we excluded elderly adult patients with associated cardiac lesions to be repaired and pediatric patients under 9 months old. Now, we think a body weight of 10 kg or more is enough to avoid perioperative homologous blood transfusion in pediatric to middle-aged adult patients.

Particularly for adult congenital heart disease patients, authorized institutions conducting percutaneous trans-catheter device closures are increasing, which provides more patients with the ability to undergo catheter intervention rather than surgical closure [18]. Also, the indication of catheter intervention for concomitant lesions like arrhythmia, heart valve disease, and patent ductus arteriosus is spreading as shown in this study. The

avoidance of open-heart surgery seems to be beneficial for patients, if therapeutic effect is equally obtained and complications seldom occur, as opposed to surgical treatment. Careful follow-up should be continued to establish an accurate treatment guideline in consideration of the safety and feasibility of both therapeutic options.

Conclusion

Percutaneous trans-catheter ASD closure with ASO was safely performed under the support of a surgical team. The cosmetic outcome of surgical closure is improving after initiation of partial sternotomy via limited skin incision for the pediatric population and young adult females. Prior to the treatment, the physicians must thoroughly inform patients and families of the advantages and disadvantages of both treatment options.

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