Structural Interventions
AMPLATZER™ Septal Occluder

CLINICAL COMPENDIUM

The AMPLATZER Septal Occluder is the most studied transcatheter atrial septal defect closure device on the market today. With more than 20 years of demonstrated clinical success, and more than 750 peer-reviewed articles, the AMPLATZER Septal Occluder provides an unmatched level of clinical experience.1,2
Clinical Insights

A PUBLICATION DELIVERING CONCISE CLINICAL DATA

AMPLATZER™ SEPTAL OCCLUDER

PEDIATRIC

TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECTS IN CHILDREN AND ADULTS USING THE AMPLATZER™ SEPTAL OCCLUDER

Omeish A, Hijazi ZM. J Interv Cardiol, 2001

• This study reported on the worldwide experience closing atrial septal defects (ASDs) in children and adults using the AMPLATZER Septal Occluder as of July 2000 (n = 3535).

• Technical success was achieved in 98% of patients (3460/3535).

• The immediate closure rate was 97.4%, including those patients with complete closure, trivial residual shunt, or with small residual shunt. The closure rate increased to 99.2% at 3 months, and 100% at 3 years.

• Minor complications were encountered in 2.8% of procedures, while serious complications occurred in less than 0.3% of the cases.

COMMUNITY USE OF THE AMPLATZER™ ATRIAL SEPTAL DEFECT OCCLUDER: RESULTS OF THE MULTICENTER MAGIC ATRIAL SEPTAL DEFECT STUDY

Everett AD, et al. Pediatric Cardiology, 2009

• This study reported on the safety and results of unrestricted multi-institution routine community use of the AMPLATZER Septal Occluder for ASD closure (n = 478).

• Technical success was achieved in 96% (458/478) of patients.

• Successful closure was 99.4% (333/335) in the simple ASD group and 100% (120/120) in the complex ASD group at 24 hours post-procedure.

• Minor complications were encountered in 4.8% of procedures, while serious complications occurred in 1.1% of the cases.

TRANSCATHETER CLOSURE OF DEFECTS WITHIN THE OVAL FOSSA USING THE AMPLATZER™ SEPTAL OCCLUDER

Latiff HA, et al. Cardiol Young, 2002

• This study reviewed the short-term outcome of transcatheter closure of ASDs within the oval fossa using the AMPLATZER Septal Occluder (n = 190).

• Technical success was achieved in 100% (190/190) of patients.

• Complete occlusion was obtained in 88% (168/190) of patients at 24 hours, 96.2% (128/133) at 3 months, and 99% (103/104) at 1-year.

• Complications occurred in 2.1% (4/190) of patients, with no major complications noted on follow-up.

ASD CLOSURE WITH THE AMPLATZER™ DEVICE


• This study reported on the safety and efficacy of the AMPLATZER Septal Occluder for transcatheter closure of ASDs and fenestrated Fontan in children and adults (n = 109).

• Technical success was achieved in 94% (102/109) of patients.

• Immediately after the release of the device, color Doppler echocardiography revealed no residual shunt in 90.2% (92/102) of patients.

• Complete closure was observed in 100% (101/101) of patients at 24 hours.

• Minor complications were encountered in 3.9% (4/102) of procedures, while serious complications occurred in 1.0% (1/102) of procedures.

See Important Safety Information Referenced Within.
LONG-TERM OUTCOME OF TRANSCATHETER SECUNDUM-TYPE ATRIAL SEPTAL DEFECT CLOSURE USING AMPLATZER™ SEPTAL OCCLUDERS


- This study assessed the long-term results of percutaneous closure of secundum-type ASDs using the AMPLATZER Septal Occluder (n = 151).

- Technical success was achieved in 100% (151/151) of patients.

- Complete occlusion was achieved in 91.4% of patients at 24 hours, 98.7% at 3 months, and 99.4% at 1-year, with 100% of the defects completely closed at the 3-year follow-up.

- There were no significant complications during the study, with a median follow-up of 78 months.

TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECT WITH AMPLATZER™ DEVICE IN CHILDREN AGED LESS THAN 10 YEARS OLD: IMMEDIATE AND LATE FOLLOW-UP


- This study analyzed the efficacy and follow-up results of percutaneous closure of ASDs with the AMPLATZER Septal Occluder in children less than 10 years old (n = 27).

- Technical success was achieved in 100% (27/27) of patients.

- Complete closure was observed in 100% (27/27) of patients at the time of last follow-up, which lasted 11.59 ± 4.42 months.

- No major complications related to the procedure were reported, and minor complications were reported in 74% (2/27) of patients, both of whom had hematomas at the femoral puncture site with no clinical consequences.

- Right ventricular diameter decreased from 19.38 ± 5.29 mm preprocedure to 11 ± 1.92 mm at late follow-up (P < 0.001).

DEVICE CLOSURE OF LARGE ATRIAL SEPTAL DEFECTS REQUIRING DEVICES ≥ 20 MM IN SMALL CHILDREN WEIGHING < 20 KG


- This study reported the experience of transcatheter closure of large ASDs with the AMPLATZER Septal Occluder in small children (n = 32).

- Technical success was achieved in 97% (31/32) of patients.

- Complete closure was observed in 100% (31/31) of patients and no major complications at last follow-up, with a median follow-up of 26.8 months ± 21.8 months.

- Right ventricular internal diameter was reduced from a preprocedure value of 2.0 ± 0.17 cm to 1.3 ± 0.17 cm at the time of the last follow-up.

- Right ventricular pressure was reduced from a preprocedure value of 37.4 ± 7.9 mmHg to 28.5 ± 3.2 mmHg at the time of the last follow-up.

COMPARING THE PERFORMANCE OF AMPLATZER™ AND OCCLUDYTECH FIGULLA SEPTAL OCCLUDERS: THE PEDIATRIC POINT OF VIEW. A RETROSPECTIVE STUDY


- This study assessed the performance of the AMPLATZER Septal Occluder compared to the Occludech Figulla occluder for percutaneous closure in pediatric patients with ostium secundum ASD (2006 to 2013) (n = 110).

- Baseline average defect size was 2.1 mm larger in the AMPLATZER group (n = 50) with 12.6 ± 5.9 vs 10.5 ± 3.8 mm in the Occludech Figulla (n = 60) group, (P = 0.02).

- Technical success was 100% with both devices.

- The most common indication for needing ASD closure in both groups was right-heart enlargement. The next most common indication was presence of a large shunt (Qp/Qs > 1.5), which was more common in the AMPLATZER group (P = 0.04).

- There were 12 patients in the AMPLATZER group with fenestrated defects and 6 in the Occludech Figulla group. When comparing patients with fenestrated defects to those with non-fenestrated defects, there was a significant difference in immediate closure rates for each group.

  - In the AMPLATZER group, there was an immediate closure rate in the non-fenestrated defect sub-group of 86.9% vs 41.6% in the fenestrated defect sub-group (P < 0.004). In the Occludech Figulla group, the immediate closure rate for non-fenestrated defects was 73.6%, vs. 28.6% for those with fenestrated defects (P < 0.03).

- At 6-month follow-up, minimal-to-mild residual shunting was observed in 2 patients (4%) in the AMPLATZER group and 4 patients (6.6%) in the Occludech Figulla group (P = 0.68).

- Procedural success immediately following treatment was 76% (n = 38) for the AMPLATZER group and 68.3% (n = 41) for the Occludech Figulla group. At 12 months, it was 98% (n = 49) for the AMPLATZER group, and 96.7% (n = 58) for the Occludech Figulla group.

- Per transesophageal echocardiography, defect size was 2.1 mm larger in the AMPLATZER group (P = 0.02).
The AMPLATZER group more frequently required intra-procedural balloon sizing than the Occlutech Figulla group (92% vs. 42% respectively, \( P < 0.0001 \)).

There were no reported adverse events.

**INCREASING PROPENSITY TO PURSUE OPERATIVE CLOSURE OF ATRIAL SEPTAL DEFECTS FOLLOWING CHANGES IN THE INSTRUCTIONS FOR USE OF THE AMPLATZER™ SEPTAL OCCLUDER DEVICE: AN OBSERVATIONAL STUDY USING DATA FROM THE PEDIATRIC HEALTH INFORMATION SYSTEMS DATABASE**

O’Byrne ML, Shinohara RT. *Am Heart J*, 2017

- This study assessed pediatric patients receiving either transcatheter closure or operative treatment for isolated atrial septal defect from 2007 to 2015 (n = 6,392).

- Of the total patients, 82% (n = 5,262) had transcatheter procedures and 18% (n = 1,130) had surgical treatment. Median age at treatment was 6 years.

- After adjusting for patient factors, the probability of pursuing a surgical operation for treatment between 2007 and 2012 decreased with an odds ratio of 0.95 per year (95% CI: 0.91-0.99) (\( P = .02 \)). In early 2013, this trend then reversed, corresponding with changes in the instructions for use of the AMPLATZER device. The probability of operative treatment increased annually with an OR of 1.21 and 95% CI: 1.06-1.39 (\( P = .006 \)).

- The total number of catheterization procedures increased by an average of 559 cases per year (95% CI: 417-701, \( P < .001 \)), while the total number of operative treatments did not change significantly (47 cases per year, 95% CI: −65 to 158, \( P = .34 \)).

- There was significant between-hospital (39 sites) variation in the choice between transcatheter and operative treatment, with a median OR 2.79 (95% CI 2.05-3.53; \( P < .001 \)). There was also significant inter-hospital variation in age of ASD closure (\( P < .001 \)).

- The age of patients who underwent ASD closure, regardless of the method, decreased over the study period (\( P = .04 \)).

- Hospital length of stay was shorter after transcatheter treatment (median 1 day, interquartile range [IQR] 1-1 day) than after surgery (median 3 days, IQR 3-4, \( P = .0001 \)).

- The estimated total stay was 1.2 days after transcatheter treatment compared with 3.2 days after surgery.
  - For the surgical group there was a nonsignificant trend toward increasing LOS (coefficient 1.03 per year, \( P = .06 \)). Gastrointestinal (\( P = .005 \)), hematologic (\( P = .03 \)), neurologic (\( P = .046 \)), respiratory (\( P < .001 \)), or other medical conditions (\( P < .001 \)) were all associated with increased length of stay.
  - For the transcatheter patients, gastrointestinal condition and respiratory condition were associated with increased length of stay (\( P < .001 \)).

- The transcatheter cohort tended to be older (\( P < .0001 \)), more likely to have private insurance (\( P < .001 \)), and less likely to have a history of gastrointestinal, hematologic, pulmonary, or other miscellaneous medical conditions (\( P < .001 \) for each).

- Over the study period, the average age of closure decreased (−0.1 year of age/year; 95% CI −0.2 to −0.004, \( P = .04 \)). Operative treatment, genetic syndrome, and gastrointestinal conditions were all associated with earlier ASD closure (\( P < .001 \) for each).

- Increasing patient age was associated with reduced probability of surgical treatment (OR 0.95, \( P < .001 \)). History of a respiratory condition was associated with an increased probability of surgical care (OR 2.67, \( P < .001 \)).

- Median hospitalization cost was also lower after transcatheter treatment at $15,981 (IQR $12,272-$21,053) than after operative care with $27,977 (IQR $21,208-$34,900, \( P = .0001 \)).

- Mean hospital cost was $20,045 for the transcatheter group compared with $25,608 for surgical care. For the transcatheter cohort, gastrointestinal and respiratory conditions were associated with increased total cost (\( P < .001 \)). For the surgical group, gastrointestinal, neurologic, respiratory, or other medical conditions were all associated with increased cost.

- The cost of operative treatment increased over the study duration, whereas the cost of transcatheter procedures, the length of stay for operative patients, and length of stay for transcatheter patients was unchanged.

- There was one in-hospital death following transcatheter closure; the risk was significantly less than that of surgical treatment with 5 deaths (0.4%, 95% CI 0.1% - 1.0%, \( P = .001 \)).

**DEVICE THERAPY FOR ATRIAL SEPTAL DEFECTS IN A MULTICENTER COHORT: ACUTE OUTCOMES AND ADVERSE EVENTS**


- This study assessed patients in the Congenital Cardiac Catheterization Project on outcomes for secundum ASD closure using septal occluders from 2007 to 2010 (n = 688).

- Of patients who received a single device (n = 653), 87% were occluded with the AMPLATZER device (n = 566), 5% with the Gore Helex device (n = 33), and 8% with either the CardioSEAL or STARFlex devices (n = 54). Thirty-five patients required ≥1 device.

- Complete closure occurred for 95% of patients with the first device chosen (n = 659).

- The majority of patients had an isolated defect (93%). The median left-to-right shunt was higher in the AMPLATZER group at 1.7 mm, compared to the Gore Helex group with 1.3 mm, and the CardioSEAL/STARFlex group with 1.4 mm (\( P = 0.003 \)).
• The median defect diameter was 12 mm [IQR: 8, 16] for the AMPLATZER group, 8 mm [7, 10] for the Gore Helex group, and 8 mm [5, 10] for the CardioSEAL/STARFlex group (P < 0.001).

• Median defect balloon size was 15 mm [IQR: 11, 19] for the AMPLATZER group, 10 mm [8, 12] for the Gore Helex group, and 12 mm [8, 15] for the CardioSEAL/STARFlex group (P < 0.001).

• The median defect/balloon ratio was 1.2 [IQR: 1.1, 1.4] for the AMPLATZER group, 1.3 [1.2, 1.5] for the Gore Helex group, and 1.4 [1.2, 1.8] for the CardioSEAL/STARFlex group (P < 0.001).

• Median Qp/Qs was 1.7 [IQR: 1.2, 2.3] for the AMPLATZER group, 1.4 [1.1, 1.8] for the Gore Helex group, and 1.3 [1.1, 1.8] for the CardioSEAL/STARFlex group (P = 0.003).

• There were 82 complications recorded in 76 patients (11.5%, 95% CI: 9.2%, 14.1%), with 4.7% classified as high severity (95% CI: 3.2%, 6.5%), and no deaths. A new conduction abnormality was discovered in 15 cases; in 1 it did not resolve. Device embolization occurred in 10 patients (1.5%), and transcatheter retrieval was possible in 7 of these cases. Heart block occurred in 2.1% of patients. Atrial tachy-arrhythmias were recorded in 16 patients, 7 of whom required medical or electrical conversion during the procedure. The AMPLATZER group had 3 cases of device erosion (0.5%, 95% CI: 0.1%, 1.5%).

GROWTH OF THE ATRIAL SEPTUM AFTER AMPLATZER™ DEVICE CLOSURE OF ATRIAL SEPTAL DEFECTS IN YOUNG CHILDREN


• This study (2002-2009) assessed how preprocedural septal measurements changed in patients (<13 years of age) after receiving an AMPLATZER device for transcatheter closure to treat secundum ASD, and measured the effect of somatic growth on these dimensions from (n = 33).

• All patients had a decrease in septal measurements following treatment. In 94% of patients (n = 31), the device contacted the aortic root after treatment; all of these remained in contact at follow-up. Mean follow-up was 4.6 ± 1.7 years.

• The IVC rim increased significantly over time (P = 0.035). A change in somatic growth (BSA) predicted asymmetric septal growth with increases in superior (P = 0.01) and IVC (P = 0.005) rims and no increase in the aortic or AVV rims.

• There were no complications reported.

TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECTS IN A CENTER WITH LIMITED RESOURCES: OUTCOMES AND SHORT TERM FOLLOW-UP

Putra ST, Djer MM. Iran J Pediatrics, 2015

• This study assessed the outcomes of transcatheter closure through short-term follow-up at an institution with limited resources in patients with secundum ASD from 2002 to 2014 (n = 152).

• The focus area of this study, Indonesia, has a severe deficit of cardiologic health professionals when compared to American College of Cardiology guidelines.

• Among transcatheter patients, 98% (n = 147) received the AMPLATZER Septal Occluder during treatment, 2% (n = 3) received a Heart Lifetech ASD occluder, and 2 underwent surgical operations.

• Technical success was 99.1% (n = 150).

• Procedural success immediately following treatment was 90.0% (n = 135). At the 6-month follow-up 100% of patients had complete closure as confirmed by transthoracic echocardiogram.

• Only 1 patient (0.6%) had a residual shunt, which was small, and completely closed after 6 months.

• Median patient age was 9.4 years, and the mean was 16.3 years.

• Mean procedure time was 114.04 minutes (range 43 - 274; SD 41.99). Mean flow ratio was 3.08 (1.7 - 27; SD 3.22). Mean fluoroscopy time was 32.81 minutes (1.5 - 100; SD 17.22). Atrial septal defect mean size was 19.71 mm (range 14 - 25).

• During the procedure, 4.9% (n = 5) of patients had bradycardia and 2.9% (n = 3) had supraventricular tachycardia (SVT); these cases all resolved. One patient (1.0%) had anemia and required a transfusion (1.0%).

• Device embolization occurred in 2 patients (1.3%) who required surgical intervention; the overall success rate was 98.6% (148/150). See Important Safety Information Referenced Within.
### Transcatheter Closure of Atrial Septal Defects in Children and Adults Using the Amplatzer™ Septal Occluder

**Omeish A, Hijazi ZM. J Interv Cardiol, 2001**

- This study reported on the worldwide experience closing atrial septal defects (ASDs) in children and adults using the AMPLATZER Septal Occluder as of July 2000 (n = 3535).
- Technical success was achieved in 98% of patients (3460/3535).
- The immediate closure rate was 97.4%, including those patients with complete closure, trivial residual shunt, or with small residual shunt. The closure rate increased to 99.2% at 3 months, and 100% at 3 years.
- Minor complications were encountered in 2.8% of procedures, while serious complications occurred in less than 0.3% of the cases.

### Summary of Pediatric Articles

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### Transcatheter Closure of Atrial Septal Defects in Adults ≥ 40 Years of Age: Immediate and Follow-Up Results


- This study presented the outcomes of ASD closure in adults over 40 years of age using the AMPLATZER Septal Occluder (n = 113).
- Technical success was achieved in 99.1% (112/113) of patients.
- Complete closure was observed in 90% (100/112) of patients at 6-month follow-up, with an additional 5.4% (6/112) having trivial shunt and 4.5% (5/112) having a small shunt and 0.9% having a moderate shunt (1/112).
- Minor complications were encountered in 2.7% (3/112) of procedures, while serious complications occurred in 0.9% (1/112) of the cases.
- At 6-month follow-up, the right ventricle end-diastolic dimension decreased from 35.3 mm (SD 7.6) preprocedure to 23.8 mm (SD 6.6) (P < 0.001) and the majority of patients reported improvement in their symptoms.

### Closure of Atrial Septal Defect with the Amplatzer™ Septal Occluder in Adults

**Majunke N, et al. Am J Cardiol, 2009**

- This study assessed closure of ASDs in adults with the AMPLATZER Septal Occluder (n = 650).
- Technical success was achieved in 99% (641/650) of patients.
- Complete closure was observed in 96% (547/572) of patients with a single ASD at last follow-up, with a mean follow-up of 36.3 months.
- Complications were observed in 0.5% (3/650) of patients during the procedure, and 5.2% (34/650) of patients within 30 days.
- In 140 patients, mean pulmonary and systemic blood flow (Qp/Qs) ratio measured ≥ 6 months after the procedure had decreased to 1 ± 0.3 from 1.9 ± 0.7.
- In 156 patients, mean systolic artery pressure measured ≥ 6 months after the procedure had decreased to 28.3 ± 10.1 mmHg from 33.3 ± 10.6 mmHg.

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See Important Safety Information Referenced Within.
ASD CLOSURE WITH THE AMPLATZER™ DEVICE


- This study reported on the safety and efficacy of the AMPLATZER Septal Occluder for transcatheter closure of ASDs and fenestrated Fontan in children and adults (n = 102).
- Immediately after the release of the device, color Doppler echocardiography revealed no residual shunt in 90.2% (92/102) of patients.
- Complete closure was observed in 100% (101/101) of patients at 24 hours.
- Minor complications were encountered in 3.9% (4/102) of procedures, while serious complications occurred in 1.0% (1/102) of the cases.

TRANSCATHETER DEVICE CLOSURE OF ATRIAL SEPTAL DEFECTS IN PATIENTS OLDER THAN 60 YEARS OF AGE: IMMEDIATE AND FOLLOW-UP RESULTS


- This study reported on transcatheter closure of ASDs in elderly patients over 60 years of age using the AMPLATZER Septal Occluder (n = 41).
- Technical success was achieved in 100% (41/41) of patients.
- Complete closure was observed in 97% (33/34) of patients at the time of the last follow-up, with a median follow-up of 28 months.
- Minor complications were encountered in 22% (9/41) of procedures, and serious complications occurred in 2.4% (1/41) of procedures.
- At a median interval of 6 months after closure, the right ventricular end-diastolic dimension decreased from 38.9 ± 9 mm preprocedure to 26.6 ± 7 mm (P < 0.001) postprocedure, and 89% of the patients showed improvement in symptoms.

TRANSVENOUS CLOSURE OF MODERATE AND LARGE SECUNDUM ATRIAL SEPTAL DEFECTS IN ADULTS USING THE AMPLATZER™ SEPTAL OCCLUDER


- This study assessed the feasibility of using the AMPLATZER Septal Occluder for closure of moderate and large secundum ASDs in adults (n = 50).
- Technical success was achieved in 100% (50/50) of patients in whom transcatheter closure was attempted.
- Complete closure was observed in 90% of patients at 1-month, 92% of patients at 3 months and 98% of patients at 1-year.
- Minor complications were encountered in 6% (3/50) of procedures, and no serious complications occurred.

COMPARISON OF CLINICAL OUTCOMES AFTER TRANSCATHETER VS. MINIMALLY INVASIVE CARDIAC SURGERY CLOSURE FOR ATRIAL SEPTAL DEFECT

Kodaira M, Kawamura A. *Circ J*, 2017

- This study assessed clinical outcomes for patients with secundum ASD receiving percutaneous closure compared with those treated with contemporary minimally invasive cardiac surgery (MICS) from 2000 to 2013 (n = 354).
- Procedural success at 1 month for patients who received the AMPLATZER Septal Occluder was 98% (n = 134), and for patients treated with MICS it was 100% (n = 220).
- At baseline, patients in the percutaneous group tended to be older. The size of the ASD was larger and the Qp/Qs ratio was greater in the MICS cohort. Patients treated with AMPLATZER had a higher incidence of hypertension and were more likely to have congestive heart failure before treatment.
- Significant independent predictors of major and minor complications were MICS procedure (OR: 2.91, 95% CI: 1.46–5.81; \( P = 0.002 \)) and patient age >70 years (OR: 3.50, 95% CI: 1.40–8.75; \( P = 0.008 \)).
Length of hospital stay was significantly shorter with AMPLATZER™ than MICS (3.6 vs. 7.3 days, respectively, \( P < 0.001 \)). The incidence of more than moderate persistent tricuspid regurgitation was 2% in both groups.

There were major complications in 2 patients for the AMPLATZER group (1.5%) and in 8 patients (8.5%) treated with MICS (\( P = 0.16 \)). Major complications were: myocardial infarction, cerebral infarction, cardiac perforation with tamponade, pulmonary edema, repeat operation, wound infection, bradyarrhythmia requiring permanent pacemaker implantation, and new-onset atrial arrhythmia requiring electronic or pharmacologic cardioversion.

Minor adverse events occurred in 15 patients (11.2%) in the AMPLATZER group, and 46 patients (20.9%) treated with MICS (\( P = 0.02 \)). Minor complications were: anemia requiring blood transfusion, pericardial effusion, pneumothorax, pleural effusion requiring thoracentesis, transient atrial arrhythmia, wound hematoma, and respiratory infection.

Three MICS patients experienced an incidence of postoperative cerebral infarction (1.4%). There was also a device embolization in the AMPLATZER group (0.5%) due to an initially undersized device. All migraines (3%) were mild.

No deaths occurred during the study period.

### MINIMALLY INVASIVE ENDOCOPIC SURGERY VERSUS CATHER-BASED DEVICE OCCLUSION FOR ATRIAL SEPTAL DEFECTS IN ADULTS: RECONSIDERATION OF THE STANDARD OF CARE


- This study assessed the outcomes of using MICS compared with the AMPLATZER Septal Occluder as treatment for patients with ASD (2002-2014) (n = 264).
- All AMPLATZER patients had ostium secundum ASD (n = 169), whereas 84/95 patients in the MICS group had ostium secundum ASD (\( P < 0.0001 \)). The other 11 MICS patients had sin venosus ASD.
- Procedural success in the AMPLATZER group was 92.9%, and for MICS it was 98.5%.
- Baseline age was 38.3 ± 12.7 years for MICS vs 49.6 ± 15.7 for the AMPLATZER cohort (\( P < 0.0001 \)). There were significantly more patients in the AMPLATZER group who suffered from diabetes at baseline (\( P = 0.02 \)). Significantly more patients in the MICS group had post-stroke status vs AMPLATZER patients (n = 18 [18.9%] vs n = 7 [4.1%]; \( P < 0.0001 \)).
- Extracorporeal circulation duration was 109.9 ± 33.6 min, with an average operation time of 228.4 ± 55.8 min. In 81% of patients (77/95) closure was performed under cardioplectic arrest, with a mean duration of aortic cross clamping of 47.7 ± 30.6 minutes. In 75.8% of patients (72/95), a pericardial patch plasty was performed, while in 24.2% (23/95) closure was achieved by direct suture techniques.
- There was a significantly higher rate of residual defect found in the AMPLATZER group at 3 months (0% vs. 30.8%, \( P < 0.0001 \)), at 6 months (0% vs. 15.9%, \( P < 0.0001 \)), and following 12 months (0% vs. 7.1%, \( P = 0.005 \)).
- A significantly higher rate of new-onset atrial fibrillation occurred in the AMPLATZER group vs MICS (9.5% vs 0%, \( P = 0.0008 \)).
- A higher rate of postprocedural oral anticoagulation use was seen at discharge (\( P = 0.004 \)) and at 3-month follow-up (\( P = 0.0002 \)) in the AMPLATZER group.
- In the AMPLATZER cohort, 1 patient had a dislocated occluder which had to be surgically removed.
- Surgery-related complications were observed in 6 (6.3%) patients, consisting of 2 cases of thoracic wound infections (2.1%), 3 access site complications (3.2%), and 1 pacemaker implantation due to atrioventricular block (1.1%). No deaths were reported during the study.

### CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECTS WITH THE AMPLATZER™ SEPTAL OCCLUDER: A PROSPECTIVE, MULTICENTER, POST-APPROVAL STUDY

Turner DR, Owada CY. *Circ Cardiovasc Interv*, 2017

- This study evaluated medium-term survival data for patients who received an AMPLATZER Septal Occluder implant. Patients were enrolled between 2008 and 2012 and were followed for 2 years (n = 1000).
- Procedural success after 1 month was 98.5%; the 2-year success rate was 97.9%.
- There were a total of 7 episodes of hemodynamic compromise in 6 patients over the 2-year follow-up; all of these events occurred within 1 year of surgery. Device erosion comprised 3 of these cases (0.3% of patients).
- Patients with an appropriately sized disk (according to sizing recommendations) were significantly less likely to develop hemodynamic compromise compared with those who had under- or oversized devices (\( P = 0.03 \)). The upper bound of the 95% confidence interval for hemodynamic compromise was 1.40%.
- Device-related adverse events totaled 56 in 46 patients, plus an additional 5 adverse events associated with the delivery system (total, 6.6%). Pericardial effusion was experienced by 31 patients; 81% of these individuals were treated with outpatient observation.
- At 2-year follow-up, there were no device, delivery system, or procedure-related deaths.
DEFICIENT SURROUNDING RIMS IN PATIENTS UNDERGOING TRANSCATHETER ATRIAL SEPTAL DEFECT CLOSURE


- This study assessed the influence of having a deficient surrounding rim on clinical outcomes and procedural success in ostium secundum ASD patients receiving percutaneous closure with the AMPLATZER™ Septal Occluder (2007-2013) (n = 474).
  - Technical success was 98% (n = 463).
  - Procedural success varied significantly among the sufficient (without deficient rim, n = 101) patient group, single defect (n = 338), and multiple (n = 35) defect groups (100%, 98%, and 86%, respectively, \( P < .001 \)).
  - At \( \geq 6 \)-months, 81 patients maintained procedural success in the sufficient group (n = 87, 93%), 249 patients in the single group (n = 287, 87%), and 21 patients in the multiple-defect group (n = 24, 88%).
  - Deficient IVC rims were present with or without additional deficient rims in 48 patients. Complete IVC rim deficiency occurred in 12 patients (IVC rim = 0 mm). There were 36 patients with present though insufficient IVC rims (1 mm \( \leq \) IVC rim \( \leq \) 4 mm). Of the 48 patients with deficient IVC rims, 43 (90%) had successful procedures.
  - A further breakdown of procedural success rates are as follows: There were 318 RAo rim-deficient patients (n = 323, 98%), 14 IVC rim-deficient patients (n = 15, 93%), 29 RAo + IVC rim-deficient patients (n = 33, 88%), and 1 patient with RAo + AVV rim deficiency (n = 2, 50%).
  - There was a significant difference in the maximal defect diameter among the sufficient, single, and multiple groups (15 ± 6, 18 ± 6, and 29 ± 7 mm, respectively, \( P < .001 \)).
  - There was also a significant difference in pulmonary-to-systemic flow ratio between the 3 groups (\( P < .001 \)). Balloon sizing was less likely to be carried out in the multiple defect group (\( P < .001 \)). Overall, deficient rims did not significantly affect intermediate-term clinical outcomes.
  - There were 11 patients with unsuccessful closure, 8 due to morphologic or technical difficulties in deploying the device in an appropriate and stable position. Major procedure-related adverse events occurred in 3 patients before hospital discharge.
  - A total of 20 cardiovascular events occurred (4%). Adverse events occurred in 26 patients (6%). There were 8 deaths (2%).

RELATIVE RISK FACTORS FOR CARDIAC EROSION FOLLOWING TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECTS: A CASE-CONTROL STUDY

McElhinney DB, Quartermain MD. *Circulation*, 2016

- This study assessed relative risk factors for cardiac erosion in patients with reported ASD closure due to an AMPLATZER Septal Occluder from 2002 to 2014 (n = 125).
  - The median duration to erosion after implant was 14 days, though this figure was >1 year in 16 patients and >5 years for 6. For 40 patients, this figure was \( \leq 1 \) day.
  - Conditions associated with erosion were: larger balloon-sized ASD diameter, AMPLATZER Septal Occluder device size, device size–ASD diameter difference, and smaller weight-to-device-size ratio. Using multivariable analysis, deficiency of any rim, device >5 mm larger than ASD diameter, and weight-to-device-size ratio were associated with erosion. Aortic rim deficiency was nearly universal among patients with erosion.
  - There were more aortic and superior vena cava rim deficiencies in cases of ASD closure than in controls. There were 100 patients with tamponade erosion, and 18 patients had evidence of a fistula between the atrium and the aorta without pericardial fluid collection.
  - Nine patients (age \( \geq 17 \) years) died; these individuals were more likely to have oversized devices and/or erosion into the aorta (7 out of 9 deaths). The likelihood of death was not significantly associated with acuity after implant.

REMODELING PROCESS IN RIGHT AND LEFT VENTRICLE AFTER PERCUTANEOUS ATRIAL SEPTAL DEFECT CLOSURE IN ADULT PATIENTS

Balci KG, Balci MM. *Turk Kardiyl Dern Ars*, 2015

- This study evaluated acute cardiac remodeling using the AMPLATZER Septal Occluder in patients with secundum ASD who received transcatheter closure between 2011 and 2013 (n = 19).
  - The mean defect diameter was 17.13 ± 5.52 mm, mean Qp/Qs was 2.54 ± 1.11, mean pulmonary artery systolic pressure was 44.31 ± 12.23 mmHg, and mean fluoroscopy time was 17.52 ± 5.83 minutes during treatment.
  - The left ventricle end-diastolic diameter increased from 37 ± 4 mm to 44 ± 5 mm. Compared with pre-procedure values, 1-day, 1-month, and 3-month check-ups each had a significant increase (\( P < 0.001 \)). The measurements for the right ventricle decreased after closure, from 40 ± 4 mm to 32 ± 5 mm; this was statically significant for the pre-procedural values compared to 1-day, 1-month, and 3-month check-ups (\( P < 0.001 \)).
• Two patients receiving Figulla devices experienced procedural failure due to deficient rims, and another patient had device embolization in the aorta. Residual shunt occurred in 9 out of 86 patients (small in 7; moderate in 2). Two patients developed an interatrial small shunt caused by an adjacent ASD close to the device.

• Two patients receiving Figulla devices experienced procedural failure. One case was due to a deficient posterior rim, and the second was caused by a complete atrioventricular block (which resolved after the device was extracted). During follow-up, shunt was observed in only 1 patient.

TRANSCATHETER CLOSURE OF ATRIAL SEPTAL DEFECT WITH THE FIGULLA ASD OCCLUDER: A COMPARATIVE STUDY WITH THE AMPLATZER™ SEPTAL OCCLUDER

Godart F, Houeijeh A. Arch Cardiovasc Dis, 2015

This study assessed patients receiving the Figulla ASD occluder (n = 31) and compared this data with those receiving an AMPLATZER device (n = 100) for percutaneous ASD closure from 2009 to 2012 (n = 131).

Technical success was 93.5% (n = 29) for Figulla patients and 86% (n = 86) for AMPLATZER patients. After 36 months, the complete closure rate was 90.3% (n = 28) for those treated with the Figulla ASD occluder, and 88.0% (n = 88) for the AMPLATZER group.

Two patients receiving AMPLATZER devices experienced procedural failure due to deficient rims, and another patient had device embolization in the aorta. Residual shunt occurred in 9 out of 86 patients (small in 7; moderate in 2). Two patients developed an interatrial small shunt caused by an adjacent ASD close to the device.

Two patients receiving Figulla devices experienced procedural failure. One case was due to a deficient posterior rim, and the second was caused by a complete atrioventricular block (which resolved after the device was extracted). During follow-up, shunt was observed in only 1 patient.

MANAGEMENT OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECT IN THE ERA OF PERCUTANEOUS TRANS-CATHETER DEVICE CLOSURE: 7-YEAR EXPERIENCE AT A SINGLE INSTITUTION

Hoashi T, Yazaki S. J Cardiol, 2015

This study assessed the repair of secundum ASD in patients receiving transcatheter or surgical closure from 2005 to 2012 (n = 1,026).

There were 317 patients (31%) who underwent surgical repair, 8 of whom converted from transcatheter due to difficulties. A total of 709 (69%) patients had transcatheter device closure.

Defect diameter in patients treated with surgery was larger than those treated with transcatheter devices (transcatheter vs. surgery: 2.3 ± 0.8 vs. 2.9 ± 0.9, P < 0.001). The estimated Qp/Qs in patients treated with surgery was also greater than for transcatheter device patients (transcatheter vs. surgery: 15 ± 5 vs. 26 ± 10, P < 0.001).

The number of patients approached through partial sternotomy with limited skin incision increased year-upon-year. The length of skin incision was 5.1 ± 1.2 cm in pediatric patients weighing <15 kg (n = 40), 6.9 ± 1.9 cm in remaining pediatric patients (n = 91), and 10.0 ± 2.5 cm in young adult females (n = 10).

Surgical interventions were required in 2 patients (0.28%) in the percutaneous group after transcatheter device closure; both were safely performed without complications. Surgical closure resulted in 3 postoperative cerebral infarctions (0.95%), including 1 death (0.32%).

Soon after transcatheter closure in one patient, an embolized device was surgically retrieved from the left atrium without post-operative complications. Another patient developed left atrium-to-aorta fistula due to late erosion, necessitating removal of the implanted device and patch closure of the fistula and defect 3 months after initial treatment.

Major central nerve system events occurred in 3 patients after the surgical repair, including a 75-year-old patient with postoperative transient atrial fibrillation who developed aspiration pneumonia and died; this was not associated with cranial nerve function after closure.

One patient developed acute mitral regurgitation due to device embolization in the left atrium. The patient required device removal and mitral valve plasty; there were no postoperative complications. Another patient developed left atrium-to-aorta fistula due to late device erosion; this patient required surgical repair 3 months after treatment without sequelae or complications. No deaths occurred during the study period.
PERCUTANEOUS CLOSURE OF SECUNDUM TYPE ATRIAL SEPTAL DEFECTS: MORE THAN 5-YEAR FOLLOW-UP

Snijder RJ, Suttorp MJ. *World J Cardiol*, 201528

- This study assessed patients ≥5 years of age who received either an AMPLATZER™ Septal Occluder or CardioSEAL/STARFlex (CS/SF) for percutaneous closure of ASD from 1998 to 2006 (n = 104).

- Technical success was 98.1% (n = 102).

- Mean follow-up was 6.4 ± 3.4 years.

- The AMPLATZER group comprised 73.1% of patients (n = 76), and the CS/SF cohort was 26.9% (n = 28).

- Four major complications were observed within 6 months of treatment. Two patients (1.9%, 1 AMPLATZER, 1 CS/SF) experienced device embolization during the index hospitalization, and the other 2 (1.9%, both in the CS/SF cohort) within 6 months. These patients underwent surgical extraction and the defect was closed using a patch.

- Between 6- and 12-month follow-up, another 2 patients in the CS/SF cohort (1.9%) underwent surgical device extraction and had the defect closed with a patch. There was a large residual shunt in 1 patient which could not be closed with a second device. The other patient required rhythm surgery and device extraction.

- Within the first 12 months, 1 CS/SF patient developed recurrent thrombo-embolic events (0.9%). This 58-year-old patient had a transient ischemic attack. Because of a history of supraventricular tachyarrhythmia, the patient was already using oral anticoagulation; CTTE showed no residual right-left shunting.

- There was device migration in 4 patients, of which 2 cases occurred during the index hospitalization (1 for AMPLATZER, 1 for CS/SF). The other 2 cases of device migration were during the first 6 months of follow-up, and were both in the CS/SF cohort.

- Recurrent thrombo-embolic event rates were similar in both groups: 0.4% per follow-up year. After 12 months, there were 2 cases in the AMPLATZER group (1.9%).

- New onset supraventricular tachyarrhythmia occurred in 6.6% of the AMPLATZER group and 17.9% of the CS/SF cohort. More than 12 months after closure, there were 3 AMPLATZER patients (3.9%) with this condition.

- Three patients suffered a recurrent neurologic event with a mean follow-up of 6.4 years (0.5% per year follow-up).

- The residual right-left shunt rate at the latest follow-up (≥12 months) was 17.4% (minimal 10.9%, moderate 2.2%, severe 4.3%) for the AMPLATZER group and 45.5% (minimal 27.3%, moderate 18.2%, severe 0%) for the CS/SF group. Neither group had residual left-right shunting.

SUMMARY OF ADULT ARTICLES

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See Important Safety Information Referenced Within.
TRANSCATHETER ASD CLOSURE VS. SURGICAL CLOSURE

COMPARISON BETWEEN TRANSCATHETER AND SURGICAL CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT IN CHILDREN AND ADULTS: RESULTS OF A MULTICENTER NONRANDOMIZED TRIAL


- This study compared the safety, efficacy and clinical utility of the AMPLATZER™ Septal Occluder for closure of secundum ASDs with surgical closure (n = 596).
- 442 patients were included in the device closure group and 154 patients were included in the surgical group.
- Technical success was achieved in 95.7% (423/442) of patients for the device group, and 100% (154/154) for the surgical group (P = 0.006).
- Complete closure was observed in 97.2% (376/387) of patients in the device group at 6-month follow-up, compared with 100% (154/154) for the surgical group (P = 0.039).
- Complication rates were 7.2% (32/442) for the device group, compared with 24% (37/154) for the surgical group (P < 0.001).
- Major complication rates were 0.2% (1/442) for the device group, compared with 5.2% (8/154) for the surgical group (P < 0.001).
- Mean length of hospital stay was 1.0 ± 0.3 day for the device group and 3.4 ± 1.2 days for the surgical group (P < 0.001).

CLOSURE OF ATRIAL SEPTAL DEFECTS IN CHILDREN: SURGERY VERSUS AMPLATZER™ DEVICE IMPLANTATION


- This study compared closure and complication rates of transcatheter closure of secundum ASDs using the AMPLATZER Septal Occluder to surgery in children with secundum ASDs (n = 91).
- 47 patients were included in the device closure group, and 44 patients were included in the surgery group.
- Closure rate at discharge was 97.5% (46/47) in the device closure group, and 95.5% (42/44) in the surgery group.
- Moderate complications occurred in 2.1% (1/47) of patients in the device closure group, and 25% (11/44) of patients in the surgery group.
- No severe complications occurred in the device closure group, while the surgery group had a severe complication rate of 4.5% (2/44).
- Mean hospital stay was 2.2 ± 1.1 days in the device closure group, compared with 7.5 ± 3.1 days in the surgery group (P < 0.001).

CLINICAL OUTCOMES AND COSTS OF AMPLATZER™ TRANSCATHETER CLOSURE AS COMPARED WITH SURGICAL CLOSURE OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECTS


- This study evaluated cost-effectiveness in patients with secundum ASDs who underwent closure using either placement of an AMPLATZER Septal Occluder or surgery, utilizing TSI accounting data to estimate hospital costs (n = 80).
- 48 patients were included in the device closure group, and 32 patients were included in the surgical group.
- Procedural success was achieved in 95.8% (46/48) of patients in the device closure group, compared with 96.8% (31/32) of surgical patients (P = 0.8).
- Complications occurred in 10.4% (5/48) of patients in the device closure group, all of which were minor, compared with 31.2% (10/32) of surgical patients.

PROSPECTIVE COMPARISON OF COSTS AND SHORT TERM HEALTH OUTCOMES OF SURGICAL VERSUS DEVICE CLOSURE OF ATRIAL SEPTAL DEFECT IN CHILDREN


- This study compared device closure of isolated secundum ASDs with the AMPLATZER Septal Occluder to surgery in terms of hospital costs, clinical outcome and impact on the patient and family (n = 62).
- 43 patients were included in the device closure group and 19 patients were included in the surgery group.
- Complete closure at 3 months postprocedure was 91% in the device closure group, and 100% in the surgical group (P = 0.3).

See Important Safety Information Referenced Within.
• Recovery times were faster with the device closure group, with 84% (36/43) of patients resuming pre-admission activity levels at 1-week, compared with 21% (4/19) of patients in the surgical group ($P < 0.01$).

• Median procedure costs were similar between the groups, but higher nursing and laboratory costs contributed to a slightly higher total cost for surgical repair at Aus $12,969 compared with Aus $11,845 for the device closure group ($P = 0.03$).

**TRANSCATHETER CLOSURE AS AN ALTERNATIVE AND EQUIVALENT METHOD TO THE SURGICAL TREATMENT OF ATRIAL SEPTAL DEFECT IN ADULTS: COMPARISON OF EARLY AND LATE RESULTS**


• This study compared early and late results of ASD closure using the AMPLATZER Septal Occluder versus open-heart surgery ($n = 100$).

• 48 patients were included in the device closure group and 52 patients were included in the open-heart surgery group.

• Technical success was achieved in 94% (45/48) of patients in the device closure group, compared with 100% (52/52) of patients in the open-heart surgery group.

• Total complication rate in the open-heart surgery group and the device closure group was not significantly different (19.2% vs. 26.7%; $P = 0.383$); however, there were more serious complications in the surgical group.

• Average length of hospital stay in the device closure group was 5.4 ± 2.2 days as compared with 9.1 ± 1.2 days for surgery ($P < 0.001$).

**COMPARISON OF RESULTS AND COMPLICATIONS OF SURGICAL AND AMPLATZER™ DEVICE CLOSURE OF ATRIAL SEPTAL DEFECTS**


• This study compared the results and complications of ASD closure using the AMPLATZER Septal Occluder versus surgery ($n = 122$).

• 61 patients were included in the device closure group, and 61 patients were included in the open-heart surgery group.

• Complete closure of the ASD was achieved in 98% of patients in both groups.

• Complications occurred in 8.2% (5/61) of patients in the device closure group, compared with 19.7% (12/61) of surgical patients.

• Average length of hospital stay in the device closure group was 3 days, compared with 8 days for surgery ($P < 0.001$).

**TRANSCATHETER VERSUS SURGICAL CLOSURE OF SECUNDUM ATRIAL SEPTAL DEFECT IN ADULTS: IMPACT OF AGE AT INTERVENTION. A CONCURRENT MATCHED COMPARATIVE STUDY**


• This study compared the short- and mid-term outcomes of transcatheter closure of secundum ASDs using the AMPLATZER Septal Occluder to surgery in adults ($n = 162$).

• 54 patients were included in the device closure group and 108 patients were included in the surgery group.

• ASDs were successfully closed in 100% of patients in both groups.

• Primary event rate during follow-up was 13.2% (7/54) in the device closure group, and 25% (28/108) in the surgery group, with important comorbidities like arrhythmias being more common in the surgical group ($P = 0.001$).

**MANAGEMENT OF OSTIUM SECUNDUM ATRIAL SEPTAL DEFECT IN THE ERA OF PERCUTANEOUS TRANS-CATHETER DEVICE CLOSURE: 7-YEAR EXPERIENCE AT A SINGLE INSTITUTION**

Hoashi T, Yazaki S. *J Cardiol*, 2015

• This study assessed the repair of secundum ASD in patients receiving transcatheter or surgical closure from 2005 to 2012 ($n = 1,026$).

• There were 317 patients (31%) who underwent surgical repair, 8 of whom converted from transcatheter due to difficulties. A total of 709 (69%) patients had transcatheter device closure.

• Defect diameter in patients treated with surgery was larger than for those treated with transcatheter devices (transcatheter vs. surgery: 2.3 ± 0.8 vs. 2.9 ± 0.9, $P < 0.001$). The estimated Qp/Qs in patients treated with surgery was also greater than for transcatheter device patients (transcatheter vs. surgery: 15 ± 5 vs. 26 ± 10, $P < 0.001$).

• The number of patients approached through partial sternotomy with limited skin incision increased year-upon-year. The length of skin incision was 5.1 ± 1.2 cm in pediatric patients weighing <15 kg ($n = 40$), 6.9 ± 1.9 cm in remaining pediatric patients ($n = 91$), and 10.0 ± 2.5 cm in young adult females ($n = 10$).

• Surgical interventions were required in 2 patients (0.28%) in the percutaneous group after transcatheter device closure; both were safely performed without complications. Surgical closure resulted in 3 postoperative cerebral infarctions (0.95%), including 1 death (0.32%).
• There were major complications in 2 patients for the transcatheter device. Another patient developed left atrium-to-aorta fistula due to late erosion, necessitating removal of the implanted device and patch closure of the fistula and defect 3 months after initial treatment.

• Major central nerve system events occurred in 3 patients after the surgical repair, including a 75-year-old patient with postoperative transient atrial fibrillation who developed aspiration pneumonia and died; this was not associated with cranial nerve function after closure.

• One patient developed acute mitral regurgitation due to device embolization in the left atrium. The patient required device removal and mitral valve plasty; there were no postoperative complications. Another patient developed left atrium-to-aorta fistula due to late device erosion; this patient required surgical repair 3 months after treatment without sequelae or complications. No deaths occurred during the study period.

COMPARISON OF CLINICAL OUTCOMES AFTER TRANSCATHETER VS. MINIMALLY INVASIVE CARDIAC SURGERY CLOSURE FOR ATRIAL SEPTAL DEFECT

Kodaira M, Kawamura A. Circ J, 2017

• This study assessed clinical outcomes for patients with secundum ASD receiving percutaneous closure compared with those treated with contemporary minimally invasive cardiac surgery (MICS) from 2000 to 2013 (n = 354).

• Procedural success at 1 month for patients who received the AMPLATZER™ Septal Occluder was 98% (n = 134), and for patients treated with MICS it was 100% (n = 220).

• At baseline, patients in the percutaneous group tended to be older. The size of the ASD was larger and the Qp/Qs ratio was greater in the MICS cohort. Patients treated with AMPLATZER had a higher incidence of hypertension and were more likely to have congestive heart failure before treatment.

• Significant independent predictors of major and minor complications were MICS procedure (OR: 2.91, 95% CI: 1.40–8.75; P = 0.008).

• Length of hospital stay was significantly shorter with AMPLATZER than MICS (3.6 vs. 7.3 days, respectively, P < 0.001). The incidence of more than moderate persistent tricuspid regurgitation was 2% in both groups.

• There were major complications in 2 patients for the AMPLATZER group (1.5%) and in 8 patients (3.6%) treated with MICS (P = 0.16). Major complications were: myocardial infarction, cerebral infarction, cardiac perforation with tamponade, pulmonary edema, repeat operation, wound infection, bradyarrhythmia requiring permanent pacemaker implantation, and new-onset atrial arrhythmia requiring electronic or pharmacologic cardioversion.

• Minor adverse events occurred in 15 patients (11.2%) in the AMPLATZER group, and 46 patients (20.9%) treated with MICS (P = 0.02). Minor complications were: anemia requiring blood transfusion, pericardial effusion, pneumothorax, pleural effusion requiring thoracentesis, transient atrial arrhythmia, wound hematoma, and respiratory infection.

• Three MICS patients experienced an incidence of postoperative cerebral infarction (1.4%). There was also a device embolization in the AMPLATZER group (0.55%) due to an initially undersized device. All migraines (3%) were mild.

• No deaths occurred during the study period.

INCREASING PROPENSITY TO PURSUE OPERATIVE CLOSURE OF ATRIAL SEPTAL DEFECTS FOLLOWING CHANGES IN THE INSTRUCTIONS FOR USE OF THE AMPLATZER™ SEPTAL OCCLUDER DEVICE: AN OBSERVATIONAL STUDY USING DATA FROM THE PEDIATRIC HEALTH INFORMATION SYSTEMS DATABASE

O’Byrne ML, Shinohara RT. Am Heart J, 2017

• This study assessed pediatric patients receiving either transcatheter closure or operative treatment for isolated atrial septal defect from 2007 to 2015 (n = 6,392).

• Of the total patients, 82% (n = 5,262) had transcatheter procedures and 18% (n = 1,130) had surgical treatment. Median age at treatment was 6 years.

• After adjusting for patient factors, the probability of pursuing a surgical operation for treatment between 2007 and 2012 decreased with an odds ratio of 0.95 per year (95% CI: 0.91-0.99) (P = .02). In early 2013, this trend then reversed, corresponding with changes in the instructions for use of the AMPLATZER device. The probability of operative treatment increased annually with an OR of 1.21 and 95% CI: 1.06-1.39 (P = .006).

• The total number of catheterization procedures increased by an average of 559 cases per year (95% CI: 417-701, P < .001), while the total number of operative treatments did not change significantly (47 cases per year, 95% CI: −65 to 158, P = .34).

• There was significant between-hospital (39 sites) variation in the choice between transcatheter and operative treatment, with a median OR 2.79 (95% CI 2.05-3.53; P < .0001). There was also significant inter-hospital variation in age of ASD closure (P < .001).

• The age of patients who underwent ASD closure, regardless of the method, decreased over the study period (P = .04).
There was one in-hospital death following transcatheter treatment (median 1 day, interquartile range [IQR] 1-1 day) than after surgery (median 3 days, IQR 3-4, \( P = 0.0001 \)).

The estimated total stay was 1.2 days after transcatheter treatment compared with 3.2 days after surgery.

- For the surgical group there was a nonsignificant trend toward increasing LOS (coefficient 1.03 per year, \( P = 0.06 \)). Gastrointestinal (\( P = 0.005 \)), hematologic (\( P = 0.03 \)), neurologic (\( P = 0.046 \)), respiratory (\( P < 0.001 \)), or other medical conditions (\( P < 0.001 \)) were all associated with increased length of stay.

- For the transcatheter patients, gastrointestinal condition and respiratory condition were associated with increased length of stay (\( P < 0.001 \)).

The transcatheter cohort tended to be older (\( P < 0.0001 \)), more likely to have private insurance (\( P < 0.001 \)), and less likely to have a history of gastrointestinal, hematologic, pulmonary, or other miscellaneous medical conditions (\( P < 0.001 \) for each).

Over the study period, the average age of closure decreased (−0.1 year of age/year, 95% CI −0.2 to −0.004, \( P = 0.04 \)). Operative treatment, genetic syndrome, and gastrointestinal conditions were all associated with earlier ASD closure (\( P < 0.001 \) for each).

Increasing patient age was associated with reduced probability of surgical treatment (OR 0.95, \( P < 0.001 \)). History of a respiratory condition was associated with an increased probability of surgical care (OR 2.67, \( P < 0.001 \)).

Median hospitalization cost was also lower after transcatheter treatment at $15,981 (IQR $12,272-$21,053) than after operative care with $27,977 (IQR $21,208-$34,900, \( P = 0.0001 \)).

Mean hospital cost was $20,045 for the transcatheter group compared with $25,608 for surgical care. For the transcatheter cohort, gastrointestinal and respiratory conditions were associated with increased total cost (\( P < 0.001 \)). For the surgical group, gastrointestinal, neurologic, respiratory, or other medical conditions were all associated with increased cost.

The cost of operative treatment increased over the study duration, whereas the cost of transcatheter procedures, the length of stay for operative patients, and length of stay for transcatheter patients was unchanged.

There was one in-hospital death following transcatheter closure; the risk was significantly less than that of surgical treatment with 5 deaths (0.4%, 95% CI 0.1% - 1.0%, \( P = 0.001 \)).

MINIMALLY INVASIVE ENDOSCPIC SURGERY VERSUS CATHETER-BASED DEVICE OCCLUSION FOR ATRIAL SEPTAL DEFECTS IN ADULTS: RECONSIDERATION OF THE STANDARD OF CARE


This study assessed the outcomes of using MICS compared with the AMPLATZER Septal Occluder as treatment for patients with ASD (2002-2014) (n = 264).

All AMPLATZER patients had ostium secundum ASD (n = 169), whereas 84/95 patients in the MICS group had ostium secundum ASD (\( P < 0.0001 \)). The other 11 MICS patients had sinus venosus ASD.

Procedural success in the AMPLATZER group was 92.9%, and for MICS it was 98.5%.

Baseline age was 38.3 ± 12.7 years for MICS vs 49.6 ± 15.7 for the AMPLATZER cohort (\( P < 0.0001 \)). There were significantly more patients in the AMPLATZER group who suffered from diabetes at baseline (\( P = 0.02 \)). Significantly more patients in the MICS group had post-stroke status vs AMPLATZER patients (n = 18 [18.9%] vs n = 7 [4.1%; \( P < 0.0001 \)).

Extracorporeal circulation duration was 109.9 ± 33.6 min, with an average operation time of 228.4 ± 55.8 min. In 81% of patients (77/95) closure was performed under cardioplegic arrest, with a mean duration of aortic cross clamping of 47.7 ± 30.6 minutes. In 75.8% of patients (72/95), a pericardial patch plasty was performed, while in 24.2% (23/95) closure was achieved by direct suture techniques.

There was a significantly higher rate of residual defect found in the AMPLATZER group at 3 months (0% vs. 30.8%, \( P < 0.0001 \)), at 6 months (0% vs. 15.9%, \( P < 0.0001 \)), and following 12 months (0% vs. 7.1%, \( P = 0.005 \)).

A significantly higher rate of new-onset atrial fibrillation occurred in the AMPLATZER™ group vs MICS (9.5% vs 0%, \( P = 0.0008 \)).

A higher rate of postprocedural oral anticoagulation use was seen at discharge (\( P = 0.004 \)) and at 3-month follow-up (\( P = 0.0002 \)) in the AMPLATZER group.

In the AMPLATZER cohort, 1 patient had a dislocated occluder which had to be surgically removed.

Surgery-related complications were observed in 6 (6.3%) patients, consisting of 2 cases of thoracic wound infections (2.1%), 3 access site complications (3.2%), and 1 pacemaker implantation due to atrioventricular block (1.1%). No deaths were reported during the study.
### SUMMARY OF ARTICLES COMPARING TRANSCATHETER ASD CLOSURE TO SURGICAL CLOSURE

<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Patients - ASO (N)</th>
<th>Patients - Surgery (N)</th>
<th>Technical Success Rate - ASO (%)</th>
<th>Technical Success Rate - Surgery (%)</th>
<th>Complete Closure Rate - ASO (%)</th>
<th>Complete Closure Rate - Surgery (%)</th>
<th>Complication Rate - ASO (%)</th>
<th>Complication Rate - Surgery (%)</th>
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See Important Safety Information Referenced Within.
REFERENCES


The AMPLATZER™ Septal Occluder is a percutaneous, transcatheter, atrial septal defect closure device intended for the occlusion of atrial septal defects (ASD) in secundum position or patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

Patients indicated for ASD closure have echocardiographic evidence of ostium secundum atrial septal defect and clinical evidence of right ventricular volume overload (such as, 1.5:1 degree of left-to-right shunt or RV enlargement).

CONTRAINDICATIONS

The AMPLATZER™ Septal Occluder is contraindicated for the following:

- Any patient known to have extensive congenital cardiac anomaly which can only be adequately repaired by way of cardiac surgery.
- Any patient known to have sepsis within 1 month prior to implantation, or any systemic infection that cannot be successfully treated prior to device placement.
- Any patient known to have a bleeding disorder, untreated ulcer, or any other contraindications to aspirin therapy, unless another antiplatelet agent can be administered for 6 months.
- Any patient known to have a demonstrated intracardiac thrombosis on echocardiography (especially left atrial or left atrial appendage thrombi).
- Any patient whose size (such as, too small for transesophageal echocardiography probe, catheter size) or condition (active infection, etc.) would cause the patient to be a poor candidate for catheterization.
- Any patient where the margins of the defect are less than 5 mm to the coronary sinus, inferior vena cava rim, AV valves, or right upper lobe pulmonary vein.

WARNINGS

- Physicians must be prepared to deal with urgent situations, such as device embolization, which require removal of the device. This includes the availability of an on-site surgeon.
- Embolized devices must be removed as they may disrupt critical cardiac functions. Embolized devices should not be withdrawn through intracardiac structures unless they have been adequately collapsed within the sheath.
- Use on or before the expiration date noted on the product packaging.
- This device is sterilized using ethylene oxide and is for single use only. Do not reuse or resterilize. Attempts to resterilize the device may result in device malfunction, inadequate sterilization, or patient harm.
- Do not use the device if the packaging sterile barrier is open or damaged.
- Do not release the AMPLATZER™ Septal Occluder from the delivery cable if the device does not conform to its original configuration, or if the device position is unstable or if the device interferes with any adjacent cardiac structure (such as Superior Vena Cava (SVC), Pulmonary Vein (PV), Mitral Valve (MV), Coronary Sinus (CS), aorta (AO)). Recapture the device and redeploy. If still unsatisfactory, recapture the device and either replace with a new device or refer the patient for alternative treatment.
- Implantation of this device may not supplant the need for Coumadin™ in patients with ASD and paradoxical emboli.
- The use of echocardiographic imaging (TTE, TEE, or ICE) is required.
- Balloon sizing should be used to size the atrial septal defect using a stop-flow technique. Do not inflate the balloon beyond the cessation of the shunt (such as, stop-flow). DO NOT OVERINFLATE.
- Patients with a retro-aortic rim of less than 5 mm in any echocardiographic plane, or patients in whom the device physically impinges on (i.e. indents or distorts) the aortic root, may be at increased risk of erosion.
- Do not select a device size greater than 1.5 times the echocardiographic-derived ASD diameter prior to balloon sizing.

PRECAUTIONS

- The use of this device has not been studied in patients with patent foramen ovale.
- Use standard interventional cardiac catheterization techniques to place this device.
- Placement of the AMPLATZER™ Septal Occluder may impact future cardiac interventions, for example transseptal puncture and mitral valve repair.
- This device contains nickel-titanium alloy, which is generally considered safe. However, in vitro testing has demonstrated that nickel is released from this device for a minimum of 60 days. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Certain allergic reactions can be serious; patients should be instructed to seek medical assistance immediately if they suspect they are experiencing an allergic reaction. Symptoms may include difficulty in breathing or swelling of the face or throat. While data is currently limited, it is possible that some patients may develop an allergy to nickel if this device is implanted.

HANDLING

Store in a dry place.

PROCEDURAL

- This device should only be used by physicians who have been trained in transcatheter techniques and who should determine which patients are suitable candidates for procedures using this device.
- The physician should exercise clinical judgment in situations that involve the use of anticoagulants or antiplatelet drugs before, during, and/or after the use of this device.
- Aspirin (for example, 81 mg or 325 mg) or an alternative antiplatelet/anticoagulant is recommended to be started at least 24 hours prior to the procedure. Cephalosporin therapy is optional.
- Maintain a recommended minimum active clotting time (ACT) of 200 seconds prior to device insertion and throughout the procedure.
- If TEE is used, the patient’s esophageal anatomy must be adequate for placement and manipulation of the TEE probe.

POST-IMPLANT

- Patients should take appropriate endocarditis prophylaxis for 6 months following device implantation. The decision to continue endocarditis prophylaxis beyond 6 months is at the discretion of the physician.
- Patients should be treated with antiplatelet/anticoagulation therapy (such as aspirin) for 6 months post-implant. The decision to continue antiplatelet/anticoagulation therapy beyond 6 months is at the discretion of the physician.
- Clinical follow-up with a cardiologist and echocardiograms are recommended at implant, 1 day post-implant, pre-discharge, and again at 1 week, 1 month, 6 months, and 12 months post-implant. Immediate follow-up with a cardiologist with the onset of any new symptoms suggestive of erosion or impending erosion, and routine clinical follow-up annually thereafter is also recommended.

USE IN SPECIFIC POPULATIONS

- Pregnancy - Care should be taken to minimize the radiation exposure to the fetus and the mother.
- Nursing mothers - There has been no quantitative assessment of the presence of leachables from the device/procedure in breast milk, and the risk to nursing mothers is unknown.

MR CONDITIONAL TO 3.0 TESLA

Caution should be used if an MRI is performed with a magnetic field of >3.0 tesla.

Through non-clinical testing, the AMPLATZER™ device has been known to be MR Conditional at field strengths of 3.0 tesla or less with a maximum whole-body-averaged specific absorption rate (SAR) of 3.83 W/kg at 1.5 tesla and 5.57 W/kg at 3.0 tesla for a 20-minute exposure to a B1 of 118 µT. The AMPLATZER™ device should not migrate in this MR environment. Non-clinical testing has not been performed to rule out the possibility of migration at field strengths higher than 3.0 tesla.

In this testing, the device produced a temperature rise of 1.1°C at 1.5 tesla and 1.6°C at 5.0 tesla.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the device.

See Important Safety Information Referenced Within.
POTENTIAL ADVERSE EVENTS

Potential adverse events may occur during or after a procedure placing this device may include, but are not limited to:

- Air embolus
- Allergic dye reaction
- Anesthesia reactions
- Apnea
- Arrhythmia
- Cardiac tamponade
- Death
- Embolization
- Fever
- Hypertension/hypotension

- Infection including endocarditis
- Need for surgery
- Pericardial effusion
- Perforation of vessel or myocardium
- Pseudoaneurysm including blood loss requiring transfusion
- Tissue erosion
- Thrombus formation on discs
- Stroke
- Valvular regurgitation

See Important Safety Information Referenced Within.
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**Caution**: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available) or at https://manuals.sjm.com/ for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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