

Midterm Outcomes of Transcatheter Closure of Atrial Septal Defect Using the Amplatzer Septal Occluder in Children

AKT CHAU, BHY CHUNG, KS LUN, YF CHEUNG, TC YUNG

Abstract

Purpose: This study reports the clinical experience and midterm outcomes of transcatheter closure of secundum atrial septal defect with the Amplatzer septal occluder in children. **Methods:** From April 1998 to June 2002, 41 children (male = 14) with a median age of 11.0 years (range = 3.2-18.9 years) and median weight of 31.5 kg (range = 13.5-65 kg) underwent transcatheter closure of secundum atrial septal defect using the Amplatzer Septal Occluder after a detailed pre-implantation evaluation. The procedures were performed under general anaesthesia with fluoroscopic guidance and transesophageal echocardiographic monitoring. The size of the device deployed was determined by the balloon-stretched diameter of the defect. Patients were followed for any residual shunts and possible complications. **Results:** The mean diameter of atrial septal defect measured by transesophageal echocardiography was 14.3 ± 4.1 mm and 19.2 ± 4.7 mm by balloon-stretched diameter. The mean device diameter was 19.2 ± 4.7 mm (range = 11-30 mm). The mean fluoroscopy time was 17.3 minutes (range = 7.4 to 30 minutes) and the mean procedure time was 100 minutes (range = 35-190 minutes). All devices were successfully deployed. Two patients developed transient atrioventricular dissociation with spontaneous recovery. Complete closure rate at 24 hours, one week, one, 6 and 12 months were 83% [90% confidence limit (CL): 73-91%], 93% (90% CL: 84-97%), 95% (90% CL: 81-96%) and 97% (90% CL: 91-99%), respectively. The mean follow-up period was 46.5 ± 18.6 months (range = 10.7-86.6 months). All devices were in stable position with no late complications. **Conclusions:** Transcatheter closure of atrial septal defect using the Amplatzer Septal Occluder is safe and effective in children. The midterm results are excellent. However, long-term follow-up is needed to ascertain the absence of possible late complications.

Key words

Amplatzer septal occluder; Children; Secundum atrial septal defect; Transcatheter closure

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Introduction

Surgical repair of secundum atrial septal defect (ASD) has long been proven to be a safe procedure with low mortality.¹ However, morbidity related to cardiopulmonary bypass, post-pericardiotomy syndrome, arrhythmias, long duration of hospitalisation and permanent sternotomy scar^{2,3} can occur. Furthermore, cardiopulmonary bypass that is required in surgical closure may lead to adverse neuro-developmental consequences in young children.⁴ Therefore, transcatheter closure of ASD has become a viable and attractive alternative to surgery.

A variety of devices have been developed and tested for their efficacy for more than two decades.⁵⁻¹⁶ Variable degree of success has been reported previously. Limitations in their use included the need for large delivery systems, complicated implantation techniques, inability to reposition or recapture the device, frequent structural failure like metal frame fracture, local damage to intra-cardiac structures and dislodgement resulting in embolisation.

The Amplatzer septal occluder (ASO) is a self-expanding double-disc device with a central connection waist to stent the atrial septal defect. Preliminary human experience regarding its safety and efficiency in closing ASD has been very encouraging.¹⁷⁻¹⁹ In the present study, we sought to report the mid-term results of transcatheter closure of secundum ASD with the ASO in children.

Methods

Patients

From April 1998 to June 2002, 41 consecutive children (14 male, 27 female) with secundum ASD underwent transcatheter closure of ASD with the ASO at a median age of 11.0 years (range = 3.2-18.9 years). The median weight was 31.5 kg (range = 13.5-65.0 kg). Five patients (12%) were young children aged 3-5 years old.

All patients underwent clinical, electrocardiographic, radiographic and echocardiographic evaluation. Transthoracic echocardiography was performed in all patients and if the echocardiographic window was not satisfactory, a transesophageal echocardiogram (TEE) would be performed either before the procedure or during cardiac catheterisation. Details of echocardiographic evaluation had been reported previously from our institution.²⁰ Briefly, the morphologic characteristics of the ASD including its diameter, location, shape, the width of surrounding septal margins, length of atrial septum and relationship of the defect to adjacent important vessels and heart valves were evaluated.

The indications for transcatheter closure was the same as that for surgical closure, i.e., evidence of significant left to right shunting causing volume overloading of the right heart as evidenced by dilation of the right atrium and right ventricle on transthoracic or transesophageal echocardiography. The inclusion criteria were (i) age ≥ 3 years old, (ii) isolated or closely separated ASDs, (iii) clinical evidence of significant left-to-right shunt, (iv) a width of septal margin of ≥ 5 mm at the superior / inferior

caval veins, tricuspid / mitral valve and right pulmonary veins and (v) the atrial septum is expected to be able to accommodate the whole device.

Exclusion criteria were (i) age < 3 years, (ii) multiple or fenestrated ASD, (iii) insufficient septal margins around the ASD, (iv) other associated cardiac abnormalities that may require surgery, and (v) patients with primum or sinus venosus type of ASD. Written informed consents were obtained from patients or parents before the procedure.

The Device

Details of the device have been described previously.¹⁷⁻¹⁹ The ASO is a self-expanding, double-disc device made of 0.004 to 0.006 inch nitinol wires. The left and right atrial discs are connected by a central waist that is used to stent and thereby close the ASD. The diameter of waist is the diameter of the device. Polyester patches are sewn inside the device to induce thrombosis (Figure 1).

The Procedure

The procedure was performed under general anaesthesia with fluoroscopic and transesophageal echocardiographic guidance. Routine right heart catheterisation was performed to obtain haemodynamic data and contrast injection was done in the right upper pulmonary vein to profile the ASD. TEE was performed to evaluate the morphological characteristics of ASD. A balloon-stretched diameter (BSD) was obtained with an Amplatzer sizing balloon. The size of the device was chosen to be equal to the BSD. Standard technique of implantation which had been described earlier^{18,19} was used. In brief, after loading of the ASO on a delivery cable, the device was passed through a French 7-10 sheath that was placed in the left atrium. The left atrial disc was deployed in the left atrium and pulled gently against the atrial septum. While maintaining some traction on the delivery cable, the connecting waist was deployed at the ASD, followed by the right atrial disc (see Figure 2). The process was monitored by fluoroscopy and TEE to ensure optimal device position and that the function of heart valves or blood flow in major vessels were not affected. Stability of the device was checked by pulling and pushing the device and if the position was satisfactory, the device was released through a microscrew system. A right atrial contrast injection and TEE were repeated after release of device to detect residual shunting. Patients were discharged the next day after clinical, radiographic and transthoracic echocardiographic evaluations to check device position and residual shunting.

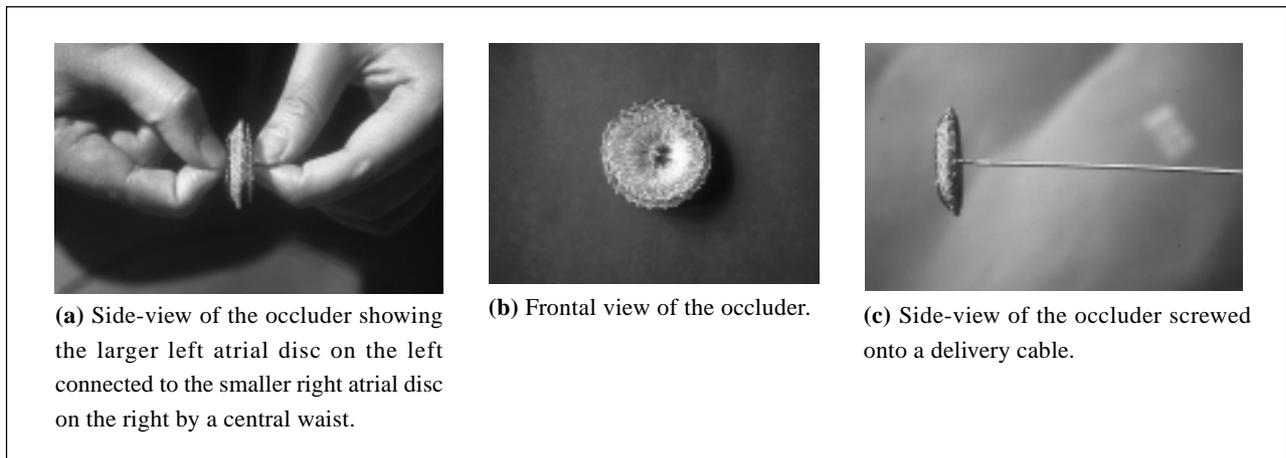


Figure 1 Amplatzer septal occluder.

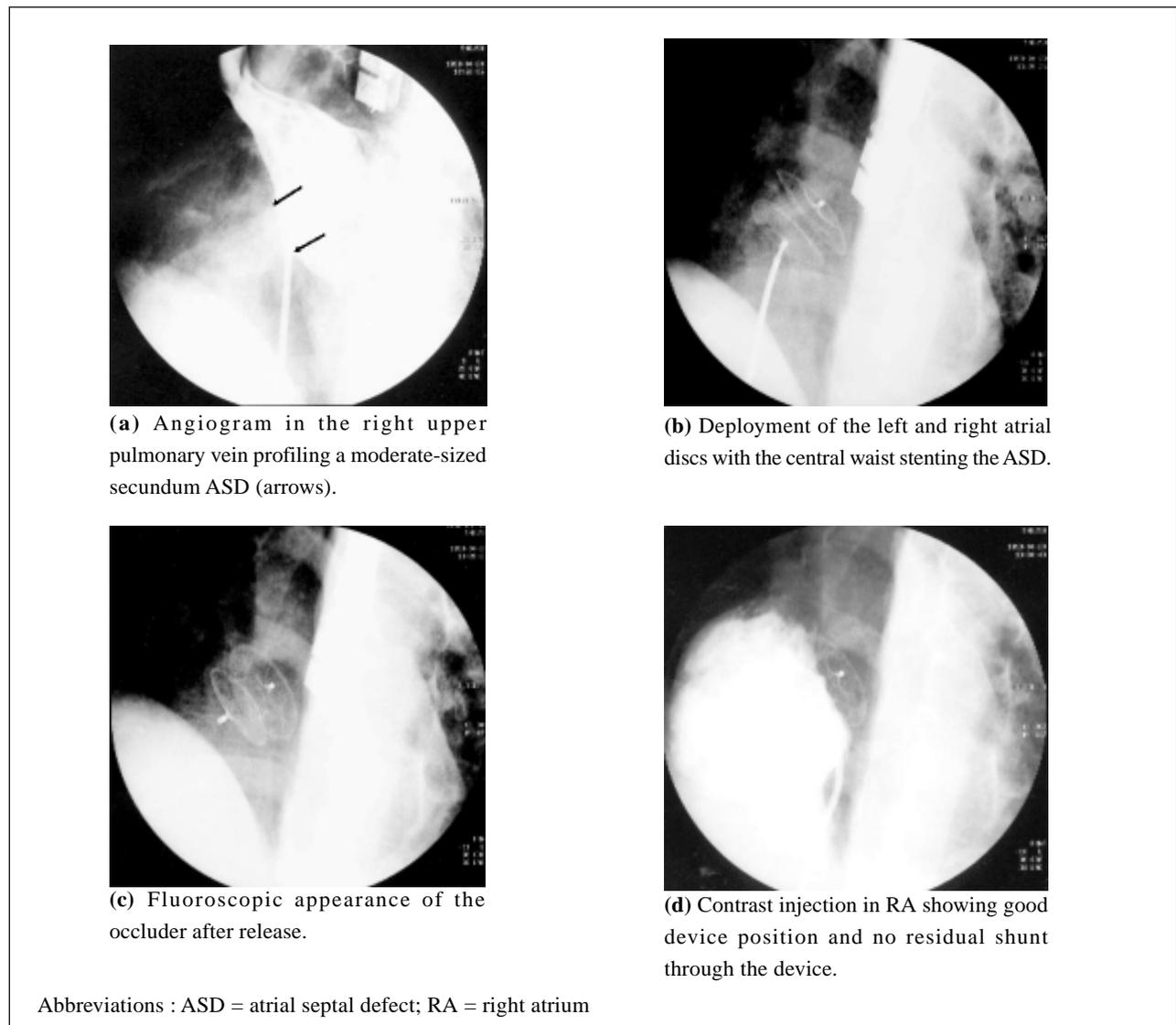


Figure 2 Transcatheter occlusion of secundum-typed atrial septal defect with the Amplatzer septal occluder.

Follow-up

All patients received anti-platelet dose of aspirin (3-5 mg/kg daily) for 6 months to prevent thromboembolism. They were reviewed at 1 week, 1, 6, 12 months and thereafter at 6 to 12 monthly intervals. Besides clinical examination, chest radiographs were taken to check device position and fracture. Electrocardiograms were repeated to detect evidence of cardiac arrhythmias. Transthoracic echocardiography was used to assess residual shunt, device position, heart valve functions and obstruction to blood flow in caval and pulmonary veins. Other possible late complications were also noted.

Statistical Analysis

Data are expressed as mean±SD. Median values and ranges were given where appropriate. Complete closure rate of ASD were expressed as percentage of total. The Kaplan Meier method was used to analyse the prevalence of residual shunt with time.

Results

All procedures including those in the five young children were successful. The mean pulmonary to systemic flow ratio (Qp/Qs) was 2.7±1.2. The mean diameter of the ASD was 14.3±4.1 mm by TEE and 19.2±4.7 mm by BSD. The device

diameter was 19.2±4.7 mm (range = 11-30 mm). The mean fluoroscopy time was 17.3 minutes (range = 7.4-30 minutes) whereas the mean procedure time was 100 minutes (range = 35-190 minutes). One patient had two closely separated ASDs that were closed with one device. Two patients developed transient atrioventricular dissociation with a slow junctional rhythm after deployment but before release of the device. Spontaneous recovery to sinus rhythm occurred within 10 minutes in both patients and the devices were released. No other immediate complications such as device embolisation were encountered.

Complete immediate closure of ASD was achieved in 27 patients (67%) and this increased to 34 patients [83%, 90% confidence limit (CL): 73-91%] at 24 hours. On follow-up, the complete closure rate was further increased to 93% (90% CL: 84-97%), 95% (90% CL: 81-96%) and 97% (90% CL: 91-99%) at 1, 6 and 12 months, respectively (Figure 3). Only one adolescent patient was found to have a small residual shunt (<2 mm in diameter on colour Doppler) at 12 months and as her transthoracic echocardiographic window became unsatisfactory, she was awaiting a TEE for confirmation of complete closure on further follow-up.

Follow-up

All patients completed follow-ups. The mean follow-up period was 46.5±18.6 months (range = 10.7-86.6 months).

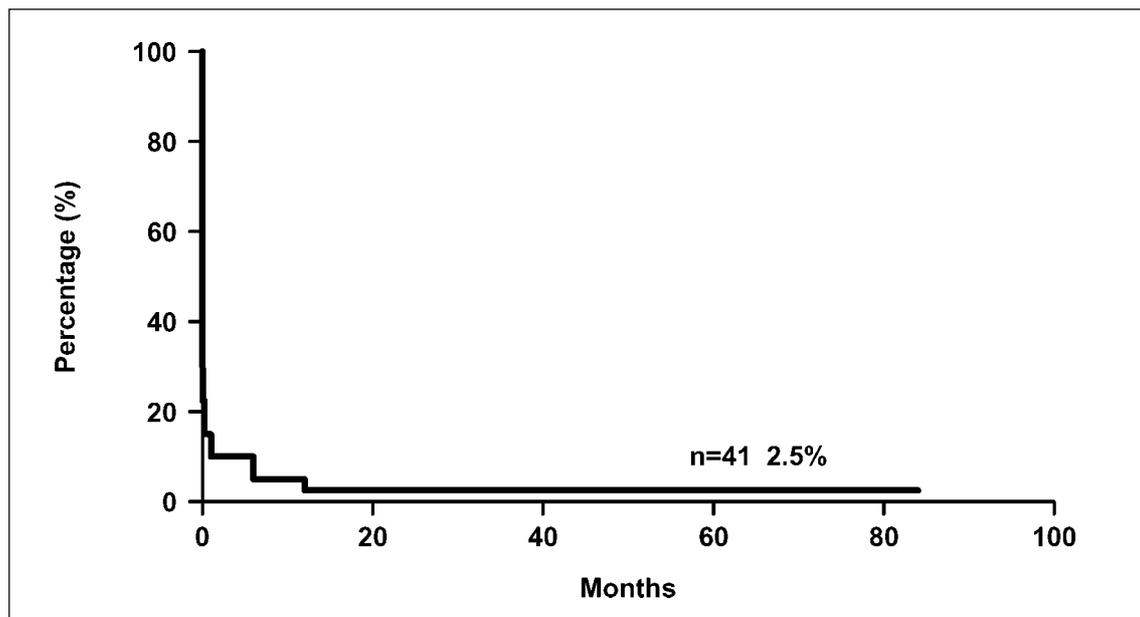


Figure 3 Prevalence of residual shunt after transcatheter occlusion of ASD with the Amplatzer septal occluder.

All devices were in stable position and there were no late complications like device embolisation, thromboembolism, pericardial effusion, cardiac perforation, infective endocarditis, cardiac arrhythmias, mitral or tricuspid valvar regurgitation or obstruction of blood flow in the caval and pulmonary veins. The two patients who developed transient atrioventricular dissociation during implantation of ASO had normal electrocardiograms during follow-up.

Discussion

The ASO is one of the most frequently used devices to close ASD and has been proven to be highly effective and safe in the short-term. Previous reports have confirmed that transcatheter closure of ASD with the ASO not only achieved a comparable efficacy and safety with that of surgical closure but has an additional advantage of causing less complications, requiring a shorter hospital stay and avoidance of a permanent scar.^{21,22} The present study showed an excellent mid-term outcome of percutaneous transcatheter closure of secundum-type of ASD using the ASO. The complete closure rate of 97% at mid-term follow-up was comparable to other reports.²³ It also showed that neither death nor major complications occurred up to mid-term follow-up, further confirming the effectiveness and safety of the procedure. Excellent long-term outcome was demonstrated in a recent report.²⁴ In our study, results of the procedure in five young children aged 3 to 5 years old was encouraging and by the time of writing this manuscript, the procedure has been extended to children as young as two years of age at our institution. Similar success of applying transcatheter closure of ASD in young children has also been reported in recent years.²⁵ To date, the use of ASO for transcatheter closure of ASD had become standard treatment in many centres where only patients not suitable for this form of treatment were sent for surgical closure. It has been estimated that 70-80% of secundum ASDs are occludable.²⁴

While mid-term outcomes are encouraging, there remain concerns on some long-term issues such as late device embolisation, thromboembolism, cardiac perforations, arrhythmias, mitral or tricuspid regurgitation, and obstruction to blood flow in caval or pulmonary veins.

Device embolisation, a well-known early complication that is commonly due to evaluation error or use of an undersized ASO, can usually be avoided. Late device embolisation due to the use of an undersized ASO for an

oval shaped ASD has been reported.²⁶ Transesophageal echocardiographic monitoring has an important role in preventing this complication.

The incidence of thromboembolism after device closure of ASD was fortunately low.^{27,28} Maintaining patients on aspirin for 6 months would reduce the risk of such a complication before complete endothelialization of the device. However, small and clinically silent thrombi may still be undetected even examining with TEE. In our study, we did not encounter any thromboembolic events.

Cardiac perforation and haemopericardium causing cardiac tamponade, a potentially life-threatening complication, has been reported to occur from several weeks to 8 months after the procedure.²⁹ It is due to late erosions, occurring at the anterosuperior or retroaortic portion of the atrial wall, and more commonly on the left atrial side of the septum. It is unclear whether this is related to a large implanted device. We think that an oversized device should be avoided in young children.

Two of our patients developed transient atrioventricular heart block with a slow junctional rhythm after deployment but before release of the ASO. Spontaneous recovery was observed within 10 minutes and the devices could be released. Should the atrioventricular block persisted, the devices would have to be retrieved. These two patients had no recurrence of cardiac arrhythmias on follow-up. So far, most of the reported cardiac arrhythmias that occur during or early after the procedure improved spontaneously or resolved on follow-up with no recurrence.^{24,30}

In our study, we did not encounter obstruction to blood flow in the caval and pulmonary vein or dysfunction of the mitral and tricuspid valves although these complications had been reported.²⁹ Careful patient evaluation and selection of an ASO of appropriate size were important factors to avoid these complications.

Conclusions

Our study confirmed that percutaneous transcatheter closure of ASD with the ASO was safe and effective. Mid-term results are excellent. The procedure can be performed safely in young children. Careful and detailed patient evaluation and selection of an ASO of appropriate size are important factors for success and avoidance of complications. However, long-term, large scale follow-up is necessary to ascertain absence of possible late complications.

References

- Kirklin JW, Barratt-Boyes BG. *Cardiac Surgery*, 2nd ed. New York, NY: Churchill Livingstones, 1993:609-44.
- Meijboom F, Hess J, Szatmari A, et al. Long-term follow-up (9 to 20 years) after surgical closure of atrial septal defect at a young age. *Am J Cardiol* 1993;72:1431-4.
- Pastorek JS, Allen HD, Davis JT. Current outcomes of surgical closure of secundum atrial septal defect. *Am J Cardiol* 1994;74:75-7.
- Visconti KJ, Bichell DP, Jonas RA, Newburger JW, Bellinger DC. Developmental outcome after surgical versus interventional closure of secundum atrial septal defect in children. *Circulation* 1999;100(19 Suppl):II145-50.
- King TD, Thompson SL, Steiner C, Mills NL. Secundum atrial septal defect. Nonoperative closure during cardiac catheterization. *JAMA* 1976;235:2506-9.
- Lock JE, Rome JJ, Davis R, et al. Transcatheter closure of atrial septal defects. Experimental studies. *Circulation* 1989;79:1091-9.
- Rome JJ, Keane JF, Perry SB, Spevak PJ, Lock JE. Double-umbrella closure of atrial defects. Initial clinical applications. *Circulation* 1990;82:751-8.
- Sideris EB, Sideris SE, Fowlkes JP, Ehly RL, Smith JE, Gulde RE. Transvenous atrial septal defect occlusion in piglets with a "buttoned" double-disk device. *Circulation* 1990;81:312-8.
- Sideris EB, Sideris SE, Thanopoulos BD, Ehly RL, Fowlkes JP. Transvenous atrial septal defect occlusion by the buttoned device. *Am J Cardiol* 1990;66:1524-6.
- Rao PS, Sideris EB, Hausdorf G, et al. International experience with secundum atrial septal defect occlusion by the buttoned device. *Am Heart J* 1994;128:1022-35.
- Rao PS, Berger F, Rey C, et al. Results of transvenous occlusion of secundum atrial septal defects with the fourth generation buttoned device: comparison with first, second and third generation devices. International Buttoned Device Trial Group. *J Am Coll Cardiol* 2000;36:583-92.
- Babic UU, Grujicic S, Popovic Z, Djuricic Z, Vucinic M, Pejic P. Double-umbrella device for transvenous closure of patent ductus arteriosus and atrial septal defect: first experience. *J Interv Cardiol* 1991;4:283-94.
- Hausdorf G, Schneider M, Franzbach B, Kampmann C, Kargus K, Goeldner B. Transcatheter closure of secundum atrial septal defects with the atrial septal defect occlusion system (ASDOS): initial experience in children. *Heart* 1996;75:83-8.
- Das GS, Voss G, Jarvis G, Wyche K, Gunther R, Wilson RF. Experimental atrial septal defect closure with a new, transcatheter, self-centering device. *Circulation* 1993;88(4 Pt 1):1754-64.
- Das GS, Hajjazi ZM, O'Laughlin MP, Mendelsohn AM, for the Investigators. Initial results of the U.S. PFO/ASD Closure Trial [abstract]. *J Am Coll Cardiol* 1996;27 Suppl A:119A.
- Pavcnik D, Wright KC, Wallace S. Monodisk: device for percutaneous transcatheter closure of cardiac septal defects. *Cardiovasc Intervent Radiol* 1993;16:308-12.
- Sharafuddin MJ, Gu X, Titus JL, Urness M, Cervera-Ceballos JJ, Amplatz K. Transvenous closure of secundum atrial septal defects: preliminary results with a new self-expanding nitinol prosthesis in a swine model. *Circulation* 1997;95:2162-8.
- Masura J, Gavora P, Formanek A, Hijazi ZM. Transcatheter closure of secundum atrial septal defects using the new self-centering amplatzer septal occluder: initial human experience. *Cathet Cardiovasc Diagn* 1997;42:388-93.
- Thanopoulos BD, Laskari CV, Tsaousis GS, Zarayelyan A, Vekiou A, Papadopoulos GS. Closure of atrial septal defects with the Amplatzer occlusion device: preliminary results. *J Am Coll Cardiol* 1998;31:1110-6.
- Chau AK, Leung MP, Yung T, Chan K, Cheung Y, Chiu S. Surgical validation and implications for transcatheter closure of quantitative echocardiographic evaluation of atrial septal defect. *Am J Cardiol* 2000;85:1124-30.
- Berger F, Vogel M, Alexi-Meskishvili V, Lange PE. Comparison of results and complications of surgical and Amplatzer device closure of atrial septal defects. *J Thorac Cardiovasc Surg* 1999;118:674-8; discussion 678-80.
- Du ZD, Hijazi ZM, Kleinman CS, Silverman NH, Larntz K; Amplatzer Investigators. Comparison between transcatheter and surgical closure of secundum atrial septal defect in children and adults: results of a multicenter nonrandomized trial. *J Am Coll Cardiol* 2002;39:1836-44.
- Omeish A, Hijazi ZM. Transcatheter closure of atrial septal defects in children & adults using the Amplatzer Septal Occluder. *J Interv Cardiol* 2001;14:37-44.
- Masura J, Gavora P, Podnar T. Long-term outcome of transcatheter secundum-type atrial septal defect closure using Amplatzer septal occluders. *J Am Coll Cardiol* 2005;45:505-7.
- Butera G, De Rosa G, Chessa M, et al. Transcatheter closure of atrial septal defect in young children: results and follow-up. *J Am Coll Cardiol* 2003;42:241-5.
- Verma PK, Thingnam SK, Sharma A, Taneja JS, Varma JS, Grover A. Delayed embolization of Amplatzer septal occluder device: an unknown entity--a case report. *Angiology* 2003;54:115-8.
- Krumsdorf U, Ostermayer S, Billinger K, et al. Incidence and clinical course of thrombus formation on atrial septal defect and patient foramen ovale closure devices in 1,000 consecutive patients. *J Am Coll Cardiol* 2004;43:302-9.
- Anzai H, Child J, Natterson B, et al. Incidence of thrombus formation on the CardioSEAL and the Amplatzer interatrial closure devices. *Am J Cardiol* 2004;93:426-31.
- Preventza O, Sampath-Kumar S, Wasnick J, Gold JP. Late cardiac perforation following transcatheter atrial septal defect closure. *Ann Thorac Surg* 2004;77:1435-7.
- Suda K, Raboisson MJ, Piette E, Dahdah NS, Miro J. Reversible atrioventricular block associated with closure of atrial septal defects using the Amplatzer device. *J Am Coll Cardiol* 2004;43:1677-82.