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Original Article

Transcatheter closure of secundum atrial septal defects: has fear of device erosion altered outcomes?

Bryan Mitchelson,[1] Clare O'Donnell,[1] Peter Ruygrok,[2] John Wright,[1] John Stirling,[1] Nigel Wilson[1]

[1]*Green Lane Paediatric and Congenital Cardiac Services, Starship Children's Hospital;* [2]*Green Lane Cardiovascular Service, Auckland City Hospital, Auckland, New Zealand*

Abstract *Background:* Transcatheter device closure has become the established standard of care for suitable atrial septal defects. Device erosion has been a recent focus and has prompted changes in the Instructions for Users documentation released by device companies. We reviewed our entire local experience with atrial septal defect device closure, focussing on the evolution of this procedure in our centre and particularly on complications. *Methods:* We carried out a retrospective review of 581 consecutive patients undergoing attempted transcatheter device closure of an atrial septal defect in Auckland from December 1997 to June 2014. We reviewed all complications recorded and compared our outcomes with the current literature. We sought to understand the impact of the evolution in recommendations and clinical practice on patient outcomes in our programme. *Results:* There were a total of 24 complications (4.1%), including 10 device embolisations (1.7%), nine arrhythmias (1.5%), two significant vascular access-related complications (0.3%), one device erosion (0.2%), one malposed device (0.2%), and one probable wire perforation of the left atrial appendage (0.2%). There was one mortality related to device embolisation. All device embolisations occurred following the change in Instructions for Users after publication of the first device erosion report in 2004. This increase in embolisation rate was statistically significant (p-value 0.015). *Conclusions:* In our series, the incidence of device embolisation was higher than that anticipated, with a significant increase following changes to the Instructions for Users. This highlights the need for ongoing data collection on complication incidence and for ongoing review of the impact of changes in clinical practice on complication rates.

Keywords: Atrial septal defect; ASD device closure; complications; embolisation

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Secundum atrial septal defects are common, with prevalence estimated at 10% of CHD.[1] Transcatheter closure of atrial septal defects was first described by King and Mills in 1976,[2] paving the way in the design of contemporary double-disc devices. Since the release of the Amplatzer Septal Occluder (AGA Medical Corporation, more recently St Jude Medical) in 1997, transcatheter closure has become the standard of care in treating atrial septal defects. Multiple, large, multi-centre trials[3–6] have demonstrated that transcatheter closure is comparable with surgical closure with respect to the rates of successful atrial septal defect occlusion achieved, but offering benefits of lower morbidity, shorter hospital stay, and greater cost-effectiveness.

Recent post-marketing surveillance studies of the Amplatzer septal occluder have focussed on its utility in closing larger defects[7,8] and the emergence of device erosion as a complication.[9–12] The Food and Drug Administration Manufacturer and User facility Device Experience group in 2004 published an incidence of 0.1% of device erosion with transcatheter closure.[11] An e-mail survey of members of the Congenital Cardiovascular Interventional Study

Correspondence to: C. O'Donnell MBChB SM, FRACP, Paediatric/Congenital Cardiologist, Paediatric and Congenital Cardiac Service, Starship/Auckland City Hospitals, Starship Children's Hospital Private Bag 92024, Victoria Street West, Auckland 1142, New Zealand. Tel: +64 9 307 4949, ext 23642/2361; Fax: +64 9 375 7026; E-mail: ClareOD@adhb.govt.nz

Consortium in 2009 found 14 cases of device erosion from 3010 implants.[13] These findings resulted in major changes in the Instructions for Users for the Amplatzer device by AGA Medical.[14]

Our team receives referrals for transcatheter closure of atrial septal defects from across New Zealand and the neighbouring Pacific Islands. In New Zealand, transcatheter closure of atrial septal defects was first introduced in 1995 at Green Lane Hospital, Auckland, using the Sideris double button umbrella device. In 1997, the Amplatzer septal occluder became available for use in New Zealand, and remains the most common device implanted for transcatheter atrial septal defect closure. This retrospective review encompasses our entire experience since 1997, with all procedures performed on children and adults included. Our specific focus was on procedural complications.

Materials and methods

Study design

A retrospective review of 581 consecutive patients at our institution who underwent an attempted transcatheter device closure of an atrial septal defect from December 1997 to the end of June 2014 was undertaken. All patients were recorded on our catheterisation database as having had a catheter procedure with a secundum atrial septal defect as the primary cardiac diagnosis and/or an interventional procedure where device closure of an atrial septal defect was recorded. Patients with patent foramen ovale or Fontan fenestration closure were excluded from the review. Patients with secundum atrial septal defect as the primary cardiac diagnosis who underwent a cardiac catheterisation study without intention to attempt transcatheter closure – for example, resistance studies in pulmonary hypertension – and those with additional important CHD – for example, pulmonary atresia intact septum – were also excluded.

Using the catheterisation database, patients selected as having had any complication related to the procedure, or where complication details were not completely recorded in the database (left blank), were identified. Subsequently, the records of patients with confirmed complications were further reviewed. Complications were classified as one of the following: device embolisation, arrhythmia, device erosion, vascular access-related, device malposition, and other/unspecified. For this review, arrhythmia was defined as the new onset of an abnormal rhythm requiring treatment – that is, brief, non-sustained arrhythmia was not reported in the database. Using knowledge of the timing of publications relating to device erosion and new recommendations from 2004, we then compared the incidence of device embolisation before and after the end of 2004, using a two-sample z-test.

Atrial septal defect device closure

Pre-catheterisation assessment. Patients were identified and referred to our institution by medical specialists around New Zealand and neighbouring Pacific Islands for consideration of transcatheter closure of an atrial septal defect. Patients were then assessed by a paediatric or adult congenital cardiologist for suitability of transcatheter atrial septal defect device closure with a detailed transthoracic echocardiogram. All adult patients were also assessed with a transoesophageal echocardiogram. On occasions, particularly in the adult group, a cardiac MRI study was requested. Our indication for intervention was the presence of right ventricular dilatation, indicating a significant left-to-right shunt, in patients where the anatomy of the defect appeared suitable for device closure by its size, location, and adequacy of surrounding rims.

Implantation Procedure. Our standard technique for device closure follows the current manufacturer's recommendations for transcatheter closure of atrial septal defects. The procedure was performed under general anaesthesia in our cardiac catheter laboratory with two cardiologists – one performing the transcatheter intervention and the second performing a transoesophageal echocardiogram during the procedure. Femoral venous access was obtained, and a right heart study was performed to measure right heart pressures and calculate the pulmonary flow-to-systemic flow ratio. All patients were initially heparinised with 100 U/kg heparin (to a maximum of 5000 U) maintaining an ACT > 200. A 0.035-inch or 0.032-inch 'J' tip guidewire, guided by an end-hole catheter, was used to cross the atrial septal defect, and positioned in the left or right upper pulmonary vein. An Amplatzer sizing balloon (initial manufacture AGA Medical Corporation, more recently St Jude Medical) was then inflated across the defect to balloon size the defect on both fluoroscopy and transoesophageal echocardiogram. Once concordance was obtained between both techniques, and no residual shunt was confirmed on the transoesophageal echocardiogram, the balloon was deflated and removed. The atrial septal defect device was then selected and deployed via the recommended delivery sheath system and positioned across the defect using fluoroscopy and transoesophageal echocardiogram guidance. Transoesophageal echocardiography was used to confirm adequate device position. Once both cardiologists agreed, the device was released. Transoesophageal echocardiography was used to make a final assessment before the sheaths/catheters were removed.

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Device type. The device chosen was at the discretion of the operator; four Cardioseal devices (NMT Medical Corporation) were implanted as part of the early experience, but the great majority of implants were with Amplatzer devices. From mid-2010, we had access to Occlutech devices (Flex-I and later Flex-II, manufactured by Occlutech). Where a complication occurred, the details of the device used were checked and recorded for this analysis. A total of five patients had two Amplatzer devices implanted. For the purposes of the analysis below they have each been counted as a single Amplatzer patient.

Patient follow-up. The day following implantation, a transthoracic echocardiogram and electrocardiogram (ECG) were performed to confirm device position and exclude any complications. Clinical and echocardiography follow-up occurred at a minimum of 1 month and 12 months following device closure. All patients included in the review had a minimum of 12 months of follow-up.

Results

Patient demographics

Transcatheter atrial septal defect device closure was performed successfully in 567 of 581 patients (98%). The demographics of patients who underwent attempted atrial septal defect device closure are comparable with other publications and are detailed in Table 1. The device type and the years during which they were implanted are as follows: Amplatzer Septal occluder 1997–2014 (n = 517), Occlutech 2010–2014 (n = 46), CardioSeal 1998 (n = 4). In 14 of 581 (2.0%) patients, a device was deployed but re-captured before release because of potential for complications. Of these, 10 cases involved very large defects requiring devices ⩾30 mm in diameter. The median age of patients was 27 years (with a range from 10 months to 78 years of age), and 361 patients (62.1%) were adults (16 years of age or older). The median device size was 20 mm (with a range from 4 to 40 mm). Large devices over 25 mm accounted for 25.6% (n = 149) of all devices implanted. The overall median procedure and fluoroscopy times are as shown in Figure 1. The annual mean procedure and fluoroscopy times have trended down since the initial device closures in 1997/98, as shown in Figure 1.

Table 1. Patient demographics (age, device size, procedure time, and fluoroscopy time expressed as medians).

Total patient number	581 patients
Successful ASD closure	567 patients (98%)
Patient age (age range)	27 years (10 months–78 years)
Gender	393 females (67.6%)
Device size (size range)	20 mm (4 mm–40 mm)
Procedure time	55 minutes (17–253 minutes)
Fluoroscopy time	11 minutes (2–105 minutes)
Complications	24 (4.1%)

ASD = atrial septal defect

Complications

There were a total of 24 complications affecting 23 patients – that is, 4.1% (95% confidence interval 2.5–5.7%). Figure 2 demonstrates the number of complications per year with the number of cases performed for that year. Of the 24 complications, there were 10 device embolisations (1.7%–95% confidence interval 0.65–2.75%), nine arrhythmias (1.5%), two vascular access-related complications (0.3%), one device erosion (0.2%), one malposed device (0.2%), and one probable wire perforation of the eft atrial appendage (0.2%). Among these, three complications occurred >24 hours after device implantation – device erosion 8 days after implantation and two embolised devices detected at 1 month and 8 months after implantation. There was one death in our case series secondary to device embolisation.

Device embolisation

Device embolisation was the most common complication following atrial septal defect device closure (cases summarised in Table 2); nine complications occurred with the Amplatzer device and one with the Occlutech device (p = 0.57). The first device embolisation occurred in 2005, just over 7 years into our experience. Of the 10 device embolisations, four occurred at the time of the procedure, two within 4 hours of the procedure, two within 24 hours of the procedure, and two occurred late (described above). Among all, three devices were successfully retrieved in the catheter laboratory. Only one of these patients had successful transcatheter device closure with a second device (of the same size), with two patients referred for later surgical closure. We retrieved seven embolised devices with the defect closure surgically, and one of the device embolisations was preceded by the onset of atrial fibrillation in the catheter laboratory, which required electrical cardioversion after device implantation at the end of the procedure. The device embolisation was detected the following day.

On review of the embolisation data in all cases the device chosen was close to the recorded balloon-sized estimate, with the largest variation being one case where a 38-mm device was implanted for an estimated 34-mm defect. Only two devices were implanted with diameter less than the estimated on balloon sizing and then only by 1 mm, and one embolisation was felt

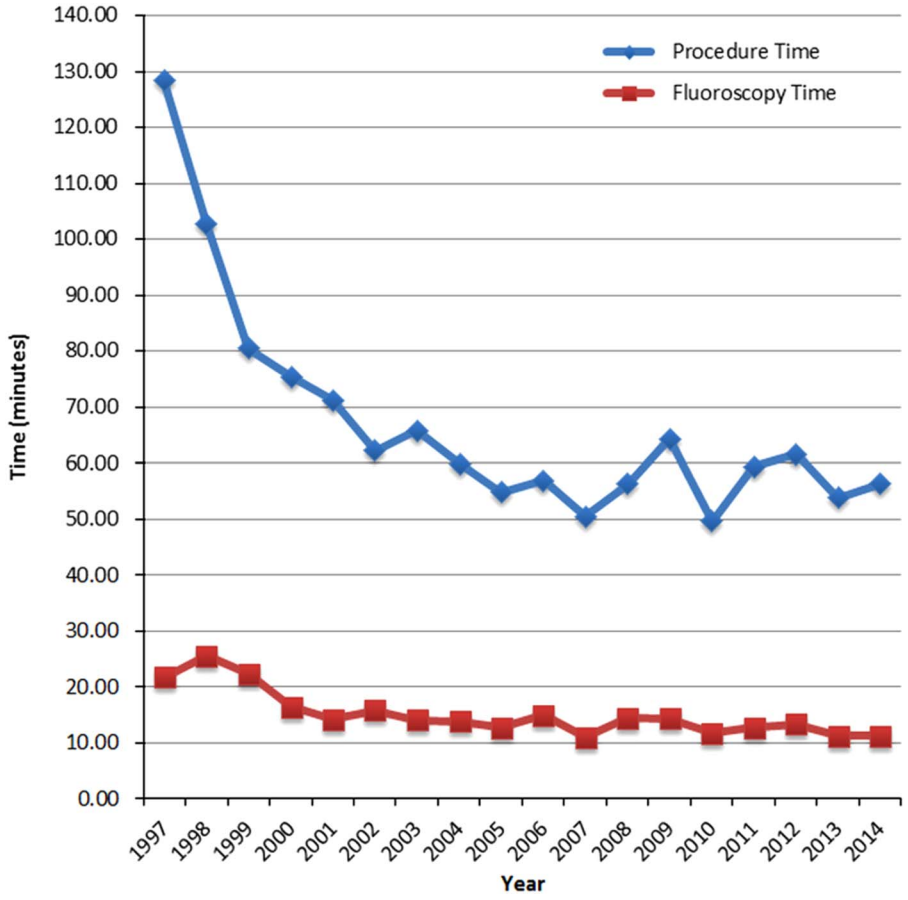

Figure 1.
Procedure time and fluoroscopy time from 1997 to 2014.

likely secondary to improper loading of the device onto the delivery cable by a trainee operator.

There was one death following device embolisation. The patient was a 24-year-old female with a background of Klippel–Feil syndrome who required particular care around the neck extension and had difficult transoesophageal echocardiogram views. The defect measured 18 mm on transoesophageal echocardiogram, and an 18-mm Occlutech device was placed. The patient was reviewed because of blood pressure instability in the recovery room and a diastolic murmur was noted. An urgent portable chest X-ray showed the device to be within the cardiac silhouette. A transthoracic echocardiogram showed no effusion but the embolised device was seen straddling the aortic valve with significant aortic regurgitation. Surgical retrieval was urgently arranged; however, before transfer, the patient had a witnessed collapse and arrest. Cardiopulmonary resuscitation was performed en-route to theatre with chest opening and cannulation performed. Important findings in theatre included tamponade with erosion of the device into the aortic root, the device still lodged across a bicuspid aortic valve, an intramural course to the origin of the left coronary artery, and a tear in septum primum tissue resulting in an increased inter-atrial defect size. The atrial septal defect and erosion were repaired at the time of surgery with device removal, and the patient was placed on an extracorporeal membrane oxygenation circuit. When evoked potentials were subsequently assessed, unfortunately no brain activity was recorded. A decision was made to withdraw extracorporeal membrane oxygenation, and the patient died 2 days after the original catheter procedure.

Over the review period, there were 10 different operators with varying levels of experience. Among them, five operators performed <20 procedures, and since 2006 these procedures have almost exclusively been performed by four operators. Embolisation events were distributed among operators with no clear relationship to volume or experience.

Before the beginning of 2005, we had performed 213 cases with no cases complicated by device embolisation. All of the 10 device embolisations have occurred from the subsequent 368 cases in our total experience (2.7% of these later implants), with this difference being statistically significant (p-value 0.015).

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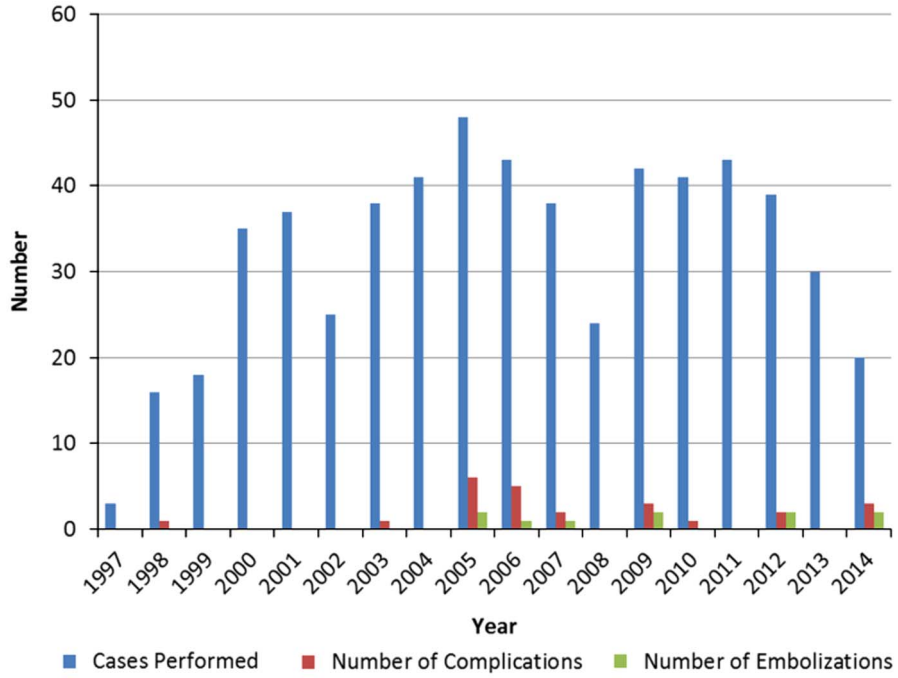

Figure 2.
Annual number of complications with number of cases performed.

Arrhythmia

Atrial arrhythmias were the second most common complications seen, with six cases of atrial flutter and three cases of atrial fibrillation (summarised in Table 3). All six episodes of atrial flutter occurred during the procedure with either catheter manipulation or during the process of implanting the atrial septal defect device. Only four patients responded to either electrical or medical cardioversion, and two patients required both electrical and medical cardioversion to achieve sinus rhythm. There was no recurrence of atrial flutter following treatment, and no long-term sequelae/treatment required. Atrial fibrillation occurred during the implantation of an atrial septal defect device in two patients and in one patient was observed immediately after device implantation. Only one patient reverted to sinus rhythm with electrical cardioversion; however, as detailed above, this patient also suffered device embolisation. At the time of surgery, cryoablation was performed across the atrial isthmus. The other two patients with atrial fibrillation received medical therapy following cardioversion, one with sotalol and warfarin and the other with amiodarone and dabigatran. In total, five patients with atrial arrhythmia had implantation of large devices (⩾25 mm) with four of these being 34-mm Amplatzer devices.

Vascular access-related complications

There were two patients with significant vascular access-related complications including a retroperitoneal haematoma and an arteriovenous fistula. The retroperitoneal haematoma resulted in temporary foot drop, but resolved with conservative management. The arteriovenous fistula required surgical repair. The records included five cases of superficial haematomas, all of which were managed conservatively and did not require blood transfusion. These were not included in our review, as they did not require intervention. In addition, we feel this likely underestimates the true incidence of superficial haematomas.

Device erosion

There was one case of late device erosion in our series of patients, occurring in an adult patient. The patient had an atrial septal defect sized at 21 mm and underwent implantation of a 22-mm Amplatzer septal occluder. The device was stable before discharge with no pericardial effusion; however the patient re-presented on day 8 with cardiac tamponade requiring urgent pericardiocentesis, transfusion, and surgery for device retrieval, repair of perforation, and closure of atrial septal defect. At operation, it was noted that there was a perforation that included the posterior wall of the aorta and the anterior roof of the left atrium. The recovery was unremarkable with no long-term sequelae.

Other complications

Device malposition was encountered in one patient aged 16 years with a very large defect. The defect

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Table 2. Case summary of device embolisations.

Date	Age (years)/ gender	Indication	ASD size	Device size (brand)	Complication details	Treatment/outcome
22 March, 2005	54/female	Symptomatic	18 mm	18 mm (Amplatzer)	Atrial fibrillation post-device implantation (successfully DCCV) Device embolised to LVOT on day 1 TTE (no obstruction)	Surgical retrieval, primary closure of ASD + cryoablation across atrial isthmus Surgery complicated by haemothorax requiring evacuation
02 August, 2005	43/male	Symptomatic	18 mm	18 mm (Amplatzer)	Immediate device embolisation to aortic arch	Retrieved by catheter Later surgical closure + tricuspid valve annuloplasty
01 August, 2006	15/male	Symptomatic	18 mm	20 mm (Amplatzer)	Premature device release from delivery cable – embolisation to pulmonary artery	Surgical retrieval and primary closure
13 February, 2007	65/male	Symptomatic + AF	24 mm	24 mm (Amplatzer)	Device embolised on day 1 TTE–straddling mitral valve (no obstruction)	Unsuccessful catheter retrieval Surgical retrieval and primary closure
19 May, 2009	46/male	Symptomatic + AF	34 mm	38 mm (Amplatzer)	Multiple manipulations to implant device Device embolised to left atrium on 4 hour TTE	Surgical retrieval and patch closure of ASD
09 June, 2009	5/male	Symptomatic	23 mm	22 mm (Amplatzer)	Immediate device embolisation to left atrium	Retrieved with snare catheter Second 22 mm Amplatzer device successfully implanted
06 December, 2012	25/female	Symptomatic	9 mm (×2)	2 × 10 mm (Amplatzer)	Both devices in situ at 24 hour TTE 1 month follow-up, 1 device in situ, other in abdominal aorta on CXR	Retrieved by catheter, not re-implanted Reassessment 18 months later–important residual shunt Surgical removal of remaining device and successful patch closure of ASD
06 December, 2012	24/female	Symptomatic + Klippel–Feil syndrome	18 mm	18 mm (Occlutech)	Hypotensive 2 hours post implantation, TTE showed device straddling aortic valve with flow obstruction Cardiac arrest en-route to theatre	Surgical retrieval of device, primary closure of ASD + repair of aortic perforation, placed on ECMO No brain activity, ECMO decannulated Died 2 days post-catheter procedure
28 January, 2014	7/female	Asymptomatic	21 mm	20 mm (Amplatzer)	Immediate embolisation of device – straddling the mitral valve	Surgical retrieval and primary closure
18 February, 2014	12/female	Symptomatic	20 mm	22 mm (Amplatzer)	Initially attempt with 20-mm device (unstable) and changed to 22-mm device Lost to follow-up, seen at 8 months with TTE showing device in LPA	Surgical retrieval and primary closure

AF = atrial fibrillation; ASD = atrial septal defect; CXR = chest X-ray; DCCV = direct current cardioversion; ECMO = extracorporeal membrane oxygenation; LPA = left pulmonary artery; LVOT = left ventricular outflow tract; TTE = transthoracic echocardiogram

Table 3. Case summary of arrhythmia complications.

Age (years)/ gender	Indication	Device size (Brand)	Complication details	Treatment/outcome
4/female	Asymptomatic	22 mm (Amplatzer)	Atrial flutter with catheter manipulations before device implantation	DCCV + Amiodarone Successful cardioversion
54/female	Symptomatic	18 mm (Amplatzer)	Atrial fibrillation following release of device	2 × DCCV – successful cardioversion Later device embolisation (see Table 2)
20/female	Asymptomatic	34 mm (Amplatzer)	Atrial flutter on device deployment	Amiodarone Successful cardioversion
52/female	Asymptomatic	20 mm (Amplatzer)	Atrial fibrillation immediately post-device implantation	DCCV + Amiodarone Discharged on Warfarin + Sotalol
20/female	Asymptomatic	34 mm (Amplatzer)	Atrial flutter with attempts at ASD device closure Unsuccessful device closure (later closed surgically)	Amiodarone Successful cardioversion
29/female	Symptomatic	28 mm (Amplatzer)	Recurrent atrial flutter with catheter manipulation and device placement	9 × DCCV Successful cardioversion
54/male	Symptomatic	34 mm (Amplatzer)	Atrial flutter with device deployment	DCCV Successful cardioversion
59/female	Asymptomatic	22 mm (Amplatzer)	Atrial flutter during catheter manipulation	DCCV Successful cardioversion
57/male	Asymptomatic	34 mm (Amplatzer)	Atrial fibrillation with device deployment and on device release	DCCV + Amiodarone Discharged on Amiodarone + Dabigatran

ASD = atrial septal defect; DCCV = direct current cardioversion

measured up to 39 mm in some views on transoesophageal echocardiogram, thought to be an overestimate, and therefore a 34-mm Amplatzer device was selected. Before release, the device appeared stable; however, following release, the device tilted into the left atrium, causing obstruction to the right lower pulmonary vein on transoesophageal echocardiogram. The device was retrieved surgically, and the defect was closed primarily with no other complications.

The other complication in the series was a probable wire perforation before device implantation. On securing a wire position, the wire did not enter the left upper pulmonary vein in the standard fashion. A 24-mm Amplatzer device was successfully implanted; however, 2 hours following the procedure, the patient developed a large pericardial effusion with tamponade. An urgent pericardiocentesis followed by surgical exploration was performed. The latter showed a clot at the base of the left atrial appendage without an identifiable puncture site. There was no suggestion of device erosion, and the device was left in situ with no later complications.

Discussion

Our overall complication rate of 4.1% was comparable with that found in other studies using the Amplatzer device – 7.2% in a large United States multi-centre study[4] and 4.8% from the more recent large United States multi-centre Magic registry.[15] Types of complication seen were consistent with previous reports. Device embolisation and arrhythmia are most commonly reported, whereas device malposition and device erosion appear to be rare.[4,6,11] Other complications infrequently reported in the post-market surveillance of the Amplatzer septal occluder, including device thrombus and infection, including endocarditis, were not encountered in our series. From the 46 Occlutech implants, we recorded one major complication as described. There was no statistical difference in proportions of complications with the ASO and the Occlutech devices. A recent, large, multi-centre retrospective study has confirmed a low rate of complications with this device type with a 1.5% rate of intraprocedural embolisation, in addition to 5 or 0.4% late embolisation, no erosions seen, and significant arrhythmia during implantation requiring treatment in 16 or 1.2%.[16]

The incidence of device embolisation was observed to be greater in our group, occurring in 1.7% of total cases, with reported device embolisation in other series ranging from 0.5 to 1.1%.[4,11,17,18] The explanation for the higher incidence of device embolisation is not entirely clear. Interestingly, the first device embolisation occurred in 2005, with 217 previous device implants, and certainly our embolisation rate after 2004 and the revised Instructions for Users are demonstrably higher.[14] We speculate that the modifications to prevent device erosion may have

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resulted in a tendency to relative under-sizing of the device, resulting in an increased embolisation risk, although we are unable to support this theory from the recorded balloon sizing data. It is possible that other factors related to implanter confidence or experience may also play a role.

It may be felt that embolisation is a relatively minor complication when compared with device erosion; however, in our series, device embolisation has resulted in seven open-heart surgical procedures for device retrieval and surgical closure of the atrial septal defect, and a further two cases requiring surgical closure of their atrial septal defects following catheter retrieval of the device. In addition to this, device embolisation has also resulted in our only mortality from atrial septal defect device closure.

The incidence of atrial arrhythmia of 1.5% was modest in our patient group when compared with the early, large, multi-centre United States study, which reported an incidence of 3.4%, and the more recent single-centre review of arrhythmias following atrial septal defect device closure by Johnson et al, which reported an incidence of 5.2%.[4,19] Arrhythmia is not an uncommon event during a cardiac catheterisation procedure, and in two of our cases atrial flutter occurred with simple catheter manipulation. Most arrhythmic complications were benign with only two patients requiring ongoing treatment for atrial fibrillation following device implantation. This review was undertaken with data from our catheterisation database and we have not included data on late atrial arrhythmia recurrence.

Device erosion is a rare but very serious complication. Detailed analysis of the Manufacturer and User facility Device Experience database by DiBardino et al[11] have estimated the risk of this complication at 0.28%, which was higher than the 0.1% estimate from the earlier registry analysis by Amin et al[20] The importance of aortic rim deficiency has been highlighted in a recent case–control study, which implicated deficiency of any rim, device size >5 mm larger that atrial septal defect diameter, and weight:device size ratio as potential associations in multivariate analysis.[21] Our experience confirms this is a rare occurrence with only a single case identified. The patient profile fitted somewhat with potential multivariate risk factors identified by McIlhinney et al in that there was a deficient retroaortic rim and patient weight:device size was smaller at 2.4; however, the device size was just 4 mm greater than the static diameter (18-mm defect, 21-mm on balloon sizing by transoesophageal echocardiogram, and 22-mm device). It is clearly not possible, however, to draw additional inference from this single case.

As noted in one additional instance, an embolised device eroded through the aortic root, possibly related to cardiac compressions.

Study limitations

This article describes complete experience over almost 17 years from a single centre. It includes, however, multiple operators and evolving approaches and techniques. As congenital cardiac care in New Zealand is coordinated from a single tertiary centre, from which we have excellent networks for follow-up, it is unlikely any major late complications would have occurred without our knowledge. All operators are encouraged to enter even the most minor complications into our catheterisation database, but we recognise potential for under-reporting.

Conclusion

From our experience, transcatheter closure is an effective and safe method for managing secundum atrial septal defects in paediatric and adult patients. The incidence of device embolisation seen was higher than that anticipated, and we regard this as a potentially serious complication, resulting in both morbidity and the only mortality in our experience. Since the introduction of the early modifications to the Instructions for Users were made to reduce the risk of device erosion, our incidence of device embolisation significantly increased. Ongoing data collection and research into risk factors for device embolisation are needed to further improve safety for this common procedure.

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Conflicts of Interest

None.

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