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Transcatheter Closure of Atrial Septal Defects

Summary

- ✓ **Until recently, surgical repair was the standard treatment for an *ostium secundum* atrial septal defect (ASD), a common congenital heart defect. Closing ASDs using a device inserted via a catheter now offers another option for some patients.**
- ✓ **Limited comparative data indicate that newer approaches to transcatheter repair have a higher failure rate than that for surgery, but short-term complication rates are lower.**
- ✓ **Evidence from long-term follow-up of patients with device closure of ASDs is not yet available.**
- ✓ **Equipment and procedure costs may be higher for transcatheter closure than for surgery, but overall costs may be reduced through avoiding intensive care unit costs and through shorter hospital stays.**

The Technology

An atrial septal defect (ASD) is a common congenital heart condition involving a defect in the atrial septum [the wall separating the left and right atria (upper chambers) in the heart]. This defect allows blood to flow from the left (high pressure) atrium to the right (low pressure) atrium, a process known as a shunt. Over time, this condition is associated with an increased risk of pulmonary artery hypertension, congestive heart failure, arrhythmias and stroke.¹ This bulletin discusses transcatheter repair of the most common type of ASDs, *ostium secundum* ASDs, which are situated at or near the centre of the atrial wall.

For those with an *ostium secundum* ASD requiring treatment, either surgical repair or catheter-based closure with an occluder device may be used. Catheter-based closure is performed using echocardiography and fluoroscopic guidance to determine the size and position of the defect and to place the occluder device. Intracardiac echocardiography, with local anaesthesia, is now often used instead of transesophageal echo, as the latter requires general anaesthesia.

General anaesthesia is still used for children to ensure lack of movement when the device is released.

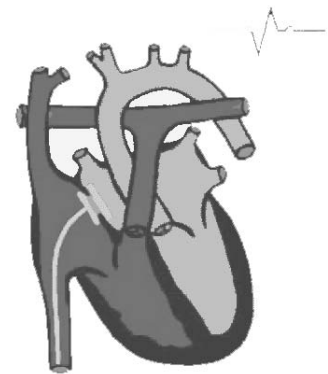


Figure 1 - ASD closure via catheter.
Reproduced with permission:
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The occluders have metal frameworks which are either fabric-covered or have woven polyester within the meshwork. The folded occluder is inserted into the heart via a catheter and opened to allow closure of the ASD. Small residual shunts after the procedure often resolve over time as the endothelial tissue grows over and around the device. The patient is usually on an anticoagulant drug, such as aspirin, for six months following the procedure.

Regulatory Status

Both the AMPLATZER® Septal Occluder System (AGA Medical Corporation) and the CardioSEAL® Septal Occlusion System (NMT

Medical, Inc.) were licensed by Health Canada in 2000 (Kathleen Savage, Health Canada, Ottawa: personal communication, 2003 Apr 23). The AMPLATZER system received pre-market approval from the US Food and Drug Administration (FDA) in 2001. The CardioSEAL system was issued a Humanitarian Device Exemption by the FDA in 2001, for repair of ASDs and other defects. It has also been granted an FDA Investigational Device Exemption in the US, for use in clinical trials assessing the device in the repair of ASDs.³

Patient Group

ASDs have been estimated to occur in one of every 1,500 live births.⁴ Determining the prevalence of ASDs can be problematic as some registries include non-clinically significant defects, while others do not.⁵ There may be regional variation in rates of ASDs. For example, the overall rate of *ostium secundum* type ASDs in Alberta, for the period 1980-1998, was 1.68 per 1,000 total births.⁶ Not all ASDs require treatment, but the closure of significant defects in children is accepted practice. A recent study of *secundum* ASDs in 104 children found that two thirds of these defects grew over time.⁷

ASDs are the most common anomalies seen in adults with congenital heart disease, and closure is frequently undertaken.⁸ However, there is continuing debate regarding patient selection and the benefits derived.⁹ Transcatheter closure has mainly been used for ASDs of up to about 40 mm, with adequate rims of septal tissue and distance from the atrioventricular valves. Du et al. recently reported successful closure rates for a small series of patients with deficient septal rims, suggesting a possible widening of the patient group eligible for transcatheter ASD repair.¹⁰

Current Practice

Transcatheter closure of ASDs is increasingly considered to be the standard of care. Formerly, surgical closure was the standard practice for

patients with *secundum* ASDs and this is still widely used.¹¹ The surgery is associated with a mortality rate of less than 1%.¹² Most ASDs in children can be closed using minimally invasive surgical techniques with a short hospital stay.¹³

The Evidence

Most evidence on the efficacy of transcatheter closure comes from case series. There are few comparative studies. Non-randomized studies^{11, 14-17} comparing transcatheter closure using the AMPLATZER device and surgery are summarized in Table 1. Patients treated surgically tended to be younger than those who had transcatheter closure. These studies showed a high success rate (often defined as no residual shunt at 3 or 12 months follow-up) for device closure, though at a rate lower than that for surgery. In some patients, placement of an occluder device was not feasible because of the size of the ASD or inadequate septal tissue. All studies found significantly fewer complications and shorter hospital stays than what was reported for surgical repair.

Adverse Effects

Transcatheter closure of ASDs is associated with risks related to the catheterization procedure, such as perforation of a blood vessel and thrombosis of the vessel, especially in small children. A further complication associated with placement of the devices is the production of air or clot emboli resulting in cerebrovascular accidents. Antiplatelet agents are used post-procedure to decrease the risk of such events. There are also risks associated with the devices themselves, such as device dislodgement, arm fracture or degradation of the metal components over time.¹⁸

Early and late complications associated with transcatheter repair were studied by Chessa et al. who followed 159 patients treated with CardioSEAL or STARFlex devices, and 258 patients who received the AMPLATZER device. Thirty four patients had complications during

Table 1: Comparisons of ASD closure with the AMPLATZER Septal Occluder System versus surgical repair

Study and patient group	Transcatheter device repair	Surgical repair	Complications	Length of stay (days)
<i>Du et al. (US)</i> € children & adults € age: 18.1 ± 19.3 yrs (device group); 5.9 ± 6.2 yrs (surgical group) € weight: 42.3 ± 27.3 kg (device group); 20.6 ± 15.2 kg (surgical group)	€ n=459 € procedural success=95.7% € closure at 12 months=98.5%	€ n=155 € procedural success=100% € closure at 12 months=100%	€ total complications: 7.2% with device, 24% with surgery € major complications: 1.6% with device, 5.4% with surgery	€ device=1.0 € surgery=3.4
<i>Cowley et al. (US)</i> € children & adults € age: 22.9 ± 20.8 yrs (device group); 10.5 ± 11.7 yrs (surgical group) € weight: 47.8 ± 31.2 kg (device group); 32.8 ± 20.8 kg (surgical group)	€ n=45 € procedural success=80% € complete closure at discharge in 25/45 patients	€ n=44 € procedural success=100% € complete closure at discharge in 42/44 patients	€ major complications: device n=0 surgery n=10	€ device=1.0 € surgery=3.6
<i>Thomson et al. (UK)</i> € children & adults € median age: 9.7 yrs (device group); 5.5 yrs (surgical group) € weight: not reported	€ n=27 € procedural success 89% (2 procedural failures and 1 device embolization) € reduction in right ventricular end diastolic diameter (RVEDD) decreased by 17.5% at 6 months	€ n=19 € procedural success 100% € RVEDD decreased by 15.1% at 6 months	€ total complications: 11% (n=3) with device, 47% (n=9) with surgery € complications affecting management: 11% (n=3) with device, 21% (n=4) with surgery	€ device=1.0 € surgery=6.0
<i>Hughes et al. (Australia)</i> € children € median age: 6.1 yrs (device group); 3.3 yrs (surgical group) € median weight: 20.2 kg (device group); 13.9 kg (surgical group)	€ n=43 € procedural success 89% € closure 91%	€ n=19 € procedural success 100% € closure 100%	€ complications: device n=2 surgery n=3	€ device=29 hrs € surgery=88 hrs
<i>Formigari et al. (Italy)</i> € children € median age: 7.0 yrs (device group); 5.1 yrs [minimally invasive (MI) surgery group]; 5.1 yrs (open surgery group) € median weight: 23 kg (device group); 20.5 kg (MI surgery group); 18 kg (open surgery group)	€ n=70 € no residual shunt=100%	€ MI surgery group n=71 € open surgery group n=50 € no residual shunt=100%	€ overall rate of complications: 3.8% (n=2) with device, 9.8% (n=7) with MI surgery, 12.0% (n=6) with open surgery	€ device=2.1 € MI surgery=2.8 € open surgery=6.5

hospitalization, eleven of which were considered major. Seven patients had device embolization (n=4 with CardioSEAL/STARFlex, n=3 with AMPLATZER) requiring surgical retrieval. Three patients underwent elective surgical repair due to malposition of the device. Eleven patients experienced arrhythmias, some of which resolved spontaneously or with electrical cardioversion. There were two late complications: peripheral embolization in a leg one year after implantation of an AMPLATZER device and a sudden death 1.5 years after the procedure (although it is not known whether this was device-related).¹⁹ A comparative study of the STARFlex and CardioSEAL devices indicated that the STARFlex device had significantly lower rates of residual shunts and device arm fractures.²⁰

An abstract by Ries et al. notes possible adverse effects associated with leaching of nickel from the AMPLATZER Septal Occluder.²¹ However, a study by Kong et al. (n=19) found no evidence of corrosion of the device *in vitro* or *in vivo*, nor were there significant elevations of blood levels of nickel in patients six months after implanting the AMPLATZER device.²² The long-term effects of an implanted device containing high levels of nickel is not known.

The use of fluoroscopy during the transcatheter closure procedure is a disadvantage, although radiation exposure is reduced with operator experience.¹¹ The risks associated with transcatheter closure should be considered in relation to those of surgical repair, which include morbidity, short

term complications and the possible loss of cognitive function associated with the need for cardiopulmonary bypass during the surgery.²³

Administration and Cost

Three studies of the AMPLATZER device (see Table 1), included cost data. The Australian study found that surgical costs were somewhat higher than those for catheter repair (AUS\$12,969 vs. AUS\$11,845).¹⁶ Thomson et al. report median costs of £5,412 for surgery and £5,375 per successful device repair, though the mean cost for device repair was £375 higher than that for surgery. This was due to the costs of the devices used in unsuccessful closure attempts and the multiple devices used in one patient.¹⁵ Formigari et al. report costs of €13,000 for device repair, €12,250 for minimally invasive surgical repair and €15,000 for open surgery.¹⁷

In Canada, AMPLATZER Septal Occluders cost C\$6,000 each (Djibril Sambou, Baylis Medical Company, Montreal: personal communication, 2003 Apr 17). The CardioSEAL occluders cost US\$5,000 each (John E. Ahern, NMT Medical, Boston: personal communication, 2003 April 29). The catheter delivery systems are an additional cost.

Concurrent Developments

Several other closure devices are undergoing clinical trials. Some of these devices are already available in Europe. These include the Atrial Septal Defect Occlusion System (ASDOS) (Dr. Osypka, GmbH), the HELEX Septal Occluder (W. L. Gore & Associates) and the STARFlex™ Septal Occluder (NMT Medical) - the modified version of the CardioSEAL device.^{20,24,25} "Patches" of polyurethane foam have also been used for transcatheter closure of ASDs, and collagen-based, resorbent patch devices are being explored.^{26,27} The use of computer-assisted, minimally invasive surgery is also being investigated for ASD closure.²⁸

Rate of Technology Diffusion

The diffusion of transcatheter procedures for ASDs will be influenced by the judgments of individual physicians regarding indications for the technology and the preferences of patients and their families. The availability of funding to cover the costs of the devices will also be a factor.

In Canada, congenital heart diseases are treated at specialist centres to which patients from other regions are referred. Currently, transcatheter device closure is only available at a small number of centres where the necessary expertise exists. Within the community of physicians treating congenital diseases in Canada, diffusion of this technology is essentially complete (Ruth Collins-Nakai, Canadian Cardiovascular Society, Ottawa: personal communication 2003 Apr 20).

Implementation Issues

The level of use of catheter-based closure procedures for ASDs will depend on the uptake by cardiac specialists, taking into account the known performance of surgical repair and the possible advantages and limitations of the alternative approach. Funding for the costs of the devices is a consideration. The preferences of patients and their families will also play a role. Key issues will be appropriate patient selection and physician training and experience in the use of these devices.²⁹

Transcatheter device closure of ASDs appears to offer benefits in the short-term, but long-term outcomes will not be known for some time. A recent German study³⁰ concluded that lifelong observation of these patients is required, as would be the case with all patients with congenital heart defects.

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