References

1. Jo SS, Han SJ, Jung MJ, Lee SJ, Seol KH, Kim GH, et al. Transcatheter closure of atrial septal defect using Amplatzer septal occluder. *Korean Circ J*. 2002;32:17-24.
2. Chessa M, Carminati M, Butera G, Bini RM, Drago M, Rosti L, et al. Early and late complications associated with transcatheter occlusion of secundum atrial septal defect. *J Am Coll Cardiol*. 2002;39:1061-5.
3. King TD, Mills NL. Nonoperative closure of atrial septal defects. *Surgery*. 1974;75:383-8.
4. Majunke N, Bialkowski J, Wilson N, Szkutnik M, Kusa J, Baranowski A, et al. Closure of atrial septal defect with the Amplatzer septal occluder in adults. *Am J Cardiol*. 2009;103:550-4.
5. 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.
6. Levi DS, Moore JW. Embolization and retrieval of the Amplatzer septal occluder. *Catheter Cardiovasc Interv*. 2004;61:543-7.

EDITORIAL COMMENTARY

Do the benefits outweigh the risks? A review of the history of atrial septal defect repairs and device closures

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The Centers for Disease Control and Prevention estimates that each year about 1966 babies are born with atrial septal defects (ASDs), representing about 5% of the 40,000 children born with some form of congenital heart defect in the United States.^{1,2} The prevalence is 6.1 ASDs/10,000 live births, with a trend toward an increase in numbers in the last decade.³ Natural history studies indicate that if left unrepaired ASDs can result in progressive right ventricular volume overload, leading ultimately to right heart failure, elevated pulmonary vascular resistance, atrial arrhythmias, systemic thromboembolic events, and ultimately death.⁴

The first successful closure of an ASD was performed by F. John Lewis in 1952 with inflow occlusion under hypothermia.⁵ Since then, the continuing innovations in surgical and cardiopulmonary bypass techniques and cardiac anesthesia have decreased mortality risk from greater than 50% in the early era to less than 0.1% in the current era,⁶ with a significant reduction in length of stay as minimally invasive techniques have come into vogue.⁷ Surgical ASD closure remains the only therapeutic option for primum ASD and sinus venosus ASD. Surgical ASD closure does carry with it the very small risk of cerebrovascular event related to air embolism during CPB and also is associated with such minor morbidities as

postpericardiotomy syndrome, postoperative bleeding, rare reoperations for recurrence, and infection.

In the past decade, there has been a trend toward transcatheter closure of ASDs, particularly secundum ASDs, with appropriate anatomy. Moore and colleagues⁸ have provided an excellent review on transcatheter device closure of ASDs, with particular emphasis on safety. The first ASD device closure was performed by King and Mills in 1974 with a Dacron polyester fabric-covered steel umbrella. Since then, these devices have gone through several iterations of shape and material.⁸ The devices most commonly used in the current era include the Amplatzer Septal Occluder (ASO; nickel and titanium alloy

Approach to decision making for management of secundum atrial septal defects.

Central Message

Ideal management of ASD requires a multidisciplinary approach that includes ASD anatomy and patient characteristics and wishes.

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wire mesh, polyester fabric filling, US Food and Drug Administration approved in 2001) and the Helex occluder (nitinol wire covered with an ultrathin polytetrafluoroethylene membrane, US Food and Drug Administration approved in 2006), both of which are self-expanding.⁸ Karamlou and colleagues⁹ analyzed the Nationwide Inpatient Sample to demonstrate a 139% increase in ASD and patent foramen ovale closures between 1988 and 2005. Surgical closure increased by a mere 24% (from 0.86/100,000 to 1.07/100,000) versus a 3475% increase (from 0.04/100,000 to 1.43/100,000) in device closures. Although the safety of surgical ASD has been established for more than half a century since routine repair of ASD on cardiopulmonary bypass became the norm on the late 1960s,⁵ with reporting of outcomes to national databases, the assessment of long-term safety of ASD devices is still ongoing. The National Cardiovascular Data registry (established in 1997) and the Improving Pediatric and Adult congenital Treatments database (IMPACT; established in 2011)¹⁰ have been established to evaluate outcomes after interventional procedures; as with most databases (including surgical databases), however, these are limited in ability for longitudinal follow-up.

Some of the documented risks of ASD device closure include temporary or permanent tachyarrhythmia and heart block (0.3%)⁸; erosions (0.28%)⁸; thromboembolic complications; device embolization (1%)¹¹; fractures; valve injury; infections; and mortality (0.05%).⁸ Device embolization is the most commonly reported event (0.2%-1%).¹¹⁻¹³ In this issue of the *Journal*, Nagre¹² reports an asymptomatic case of embolization of a 32-mm ASO, detected on routine predischARGE chest radiography 1 day after implantation. Successful surgical retrieval of the device and patch closure of the ASD were performed. The initial decision to proceed with device closure despite the size of the defect and inadequate rims was related to the patient's refusal to undergo surgical closure.

Although some studies¹⁴ have shown lower complication rates and shorter hospital stay with ASD device closure, others¹⁵ have shown higher long-term intervention rate and long-term mortality relative to surgical ASD closure. This has been borne out by Dibardino and colleagues,¹³ who queried the US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database for reported adverse events after Amplatzer ASO implantation between January 2002 and June 2007. A comparator group for surgical ASD closure was derived from the Society of Thoracic Surgeons Congenital Cardiac Database. Deriving an estimate of ASO implants on the basis of published data, they were

able to demonstrate no difference in overall mortality between the 2 groups; however, they reported a higher rate of rescue operations for the ASO when compared with reoperations for surgical ASD closures, with significantly higher mortality associated with these rescue events.

Thus the jury is still out regarding the safest way to approach secundum ASDs that need intervention. Both methods have risks and benefits, as clearly shown in this review. The ideal technique should be decided on the basis of the anatomy of the defect and patient characteristics and comorbidities, with a multidisciplinary approach including patient input.

References

- Centers for Disease Control and Prevention. Atlanta: The Centers; c2015. Congenital heart defects (CHDs): data & statistics. Available at: <http://www.cdc.gov/ncbddd/heartdefects/data.html>. Accessed August 1, 2015.
- Centers for Disease Control and Prevention. Atlanta: The Centers; c2015. Congenital heart defects (CHDs): facts about atrial septal defect. Available at: <http://www.cdc.gov/ncbddd/heartdefects/atrialseptaldefect.html>. Accessed August 1, 2015.
- Bjornard K, Riehle-Colarusso T, Gilboa SM, Correa A. Patterns in the prevalence of congenital heart defects, metropolitan Atlanta, 1978 to 2005. *Birth Defects Res A Clin Mol Teratol*. 2013;97:87-94.
- Craig RJ, Selzer A. Natural history and prognosis of atrial septal defect. *Circulation*. 1968;37:805-15.
- Alexi-Meskishvili VV, Konstantinov IE. Surgery for atrial septal defect: from first experiments to clinical practice. *Ann Thorac Surg*. 2003;76:322-7.
- The Society of Thoracic Surgeons. Chicago: The Society; c2014. STS National Database/Data Managers/Executive Summaries. Available at: <http://www.sts.org/national-database/database-managers/executive-summaries>. Accessed August 1, 2015.
- Cremer JT, Böning A, Anssar MB, Kim PY, Pethig K, Harringer W, et al. Different approaches for minimally invasive closure of atrial septal defects. *Ann Thorac Surg*. 1999;67:1648-52.
- Moore J, Hegde S, El-Said H, Beekman R III, Benson L, Bergersen L, et al; ACC IMPACT Steering Committee. Transcatheter device closure of atrial septal defects: a safety review. *JACC Cardiovasc Interv*. 2013;6:433-42.
- Karamlou T, Diggs BS, Ungerleider RM, McCrindle BW, Welke KF. The rush to atrial septal defect closure: is the introduction of percutaneous closure driving utilization? *Ann Thorac Surg*. 2008;86:1584-90; discussion 1590-1.
- Martin GR, Beekman RH, Ing FF, Jenkins KJ, McKay CR, Moore JW, et al. The IMPACT registry: Improving Pediatric and Adult Congenital Treatments. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu*. 2010;13:20-5.
- Lindsey JB, Hillis LD. Clinical update: atrial septal defect in adults. *Lancet*. 2007;369:1244-6.
- Nagre SW. Surgical removal of embolized atrial septal defect device from pulmonary artery. *J Thorac Cardiovasc Surg*. 2015;150:e55-7.
- DiBardino DJ, McElhinney DB, Kaza AK, Mayer JE Jr. Analysis of the US Food and Drug Administration Manufacturer and User Facility Device Experience database for adverse events involving Amplatzer septal occluder devices and comparison with the Society of Thoracic Surgeons congenital cardiac surgery database. *J Thorac Cardiovasc Surg*. 2009;137:1334-41.
- 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.
- Kotowycz MA, Therrien J, Ionescu-Ittu R, Owens CG, Pilote L, Martucci G, et al. Long-term outcomes after surgical versus transcatheter closure of atrial septal defects in adults. *JACC Cardiovasc Interv*. 2013;6:497-503.