Initial Kaiser Permanente Southern California Experience Embracing the New Technology of Transcatheter Closure of Atrial Septal Defects

By Ronald M Rosengart, MD
Morris M Salem, MD
Timothy L Degner, MD
Samuel O Sapin, MD

Abstract

As a result of individual physicians' initiative, transcatheter closure of secundum atrial septal defects—a new procedure—was made available to patients in the Kaiser Permanente (KP) Southern California Region soon after the US Food and Drug Administration (FDA) approved use of the AMPLATZER Septal Occluder. This ingenious device and the procedure for its implantation are described along with results of implantation in our initial 51 pediatric and adult patients. These results are compared with other published results. The clinical implications of using this new procedure are major: Many pediatric and adult patients with atrial septal defects can now benefit from nonoperative closure of these defects. On the basis of these observations, we attest to the commitment of Permanente physicians to incorporate technical advances into medical practice and to assess KP's experience using the new technology.

Introduction

Atrial septal defects are among the most common congenital cardiac anomalies in children and adults. The most common type of atrial septal defect is the ostium secundum defect, which affects the fossa ovalis in the midportion of the atrial septum. Fenestrated defects and multiple defects sometimes occur. Although results of surgical closure have been excellent for many years, interventional cardiologists have attempted to close the defect without open heart surgery. The AMPLATZER Septal Occluder device (AGA Medical Corporation, Golden Valley, Minnesota) was first used in Europe in 1995 to close ostium secundum defects; and in 1997, Masura et al[1] reported a series of 30 patients (age range 2.9 years to 62.4 years), 97% of whom had complete closure of a secundum defect and none of whom had complications. The device was approved by the FDA for use in the United States in December 2001.

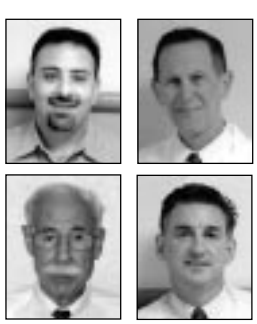
The Kaiser Permanente (KP) Southern California Region established its own diagnostic cardiac catheterization laboratory for pediatric and adult patients in 1960. Today, many therapeutic interventional procedures are being done in the laboratory, often replacing or complementing those done by surgery. In 1999, anticipating FDA approval of the AMPLATZER device, one of the authors (RMR) went to France on an extended educational leave, where he was able to learn how to implant the device. His experience was very helpful to our laboratory. Beginning in May 2002, five months after the FDA approved use of the AMPLATZER device, we started our implantation program. During the next 14 months, 51 patients (including children and adults) were identified as candidates for transcatheter closure of secundum atrial defects using the AMPLATZER device. We present this initial experience using transcatheter closure of atrial septal defects in these 51 patients.

Although results of surgical closure have been excellent for many years, interventional cardiologists have attempted to close the defect without open heart surgery.

Methods

Patient Selection

Patients were evaluated by KP cardiologists, who established the diagnosis of secundum atrial septal defect. These cardiologists also de-



Ronald M Rosengart, MD, (top, right), is Chief of the Department of Pediatrics, Los Angeles Medical Center. He is an Interventional Pediatric Cardiologist. E-mail: ronald.m.rosengart@kp.org.
Morris M Salem, MD, (top, left), is a Pediatric Interventional Cardiologist at Los Angeles Medical Center. E-mail: morris.m.salem@kp.org.
Timothy L Degner, MD, (bottom, right), is Assistant Chief of the Department of Pediatrics, Los Angeles Medical Center. He is an Interventional Pediatric Cardiologist. E-mail: timothy.l.degner@kp.org.
Samuel O Sapin, MD, (bottom, left), is retired. He was the first pediatric cardiologist in the Southern California Region. He has held many administrative positions including former Chief of Pediatrics, Panorama City Medical Center, former Associate Medical Director of Clinical Services. E-mail: samuel.o.sapin@kp.org.

termined that closure of the defect was desirable and that the AMPLATZER device was suitable for defect closure on the basis of published criteria. Except for some older adults, all patients were asymptomatic; and all patients were given their choice of surgery or transcatheter closure. Implantation was performed by pediatric cardiologists.

Description of Device Used

We used the AMPLATZER Septal Occluder, a one-piece device with three components: A cylinder (or waist) fits inside the atrial defect like a stent and is connected on each end to a saucer-shaped disk in each atrium, thus completely occluding the defect. The entire device is made from a fine nitinol (nickel-titanium alloy) wire mesh with a preformed shape. The device can be compressed to fit into a catheter and then self-expand when released inside the atria. A thin, polyester thrombogenic patch inside each of the three components prevents blood flow through the defect after the device is implanted.

Figure 1 illustrates the device and its implantation. The waist self-centers the device in the defect and stabilizes it. The left-sided disk is slightly larger than the right, and both disks grip the septal rim after implantation. The diameter of the waist determines the size of the device chosen for each patient. The device is available in sizes ranging from 4 mm to 38 mm and can be used to close a defect with stretched diameter as large as 38 mm. The center of the right atrial disk is attached to the end of a long cable by a screw-in mechanism for device delivery and is released after satisfactory positioning. Animal studies indicate that most of the devices are completely covered by endothelium in three months.

The entire procedure was done percutaneously through the femoral vein.

Description of Implantation Procedure

Most patients receiving the AMPLATZER device had general anesthesia, tracheal intubation, and transesophageal confirmation of defect size, location, and anatomy. Most recently, intracardiac echocardiography guidance has been used in nonintubated, fully awake patients. The entire procedure was done percutaneously through the femoral vein. Angiography conducted from the right-upper-lobe pulmonary vein excluded presence of an anomalous right pulmonary vein and showed the defect. A sizing balloon catheter was advanced through the atrial defect over a wire, and the balloon was expanded with a dilute solution of contrast medium to completely occlude the defect. The diameter of the stretched defect was measured to determine appropriate device size.

A long delivery sheath was advanced over the wire into the upper left pulmonary vein. The device was then loaded into the delivery sheath and advanced into the left atrium. The sheath was withdrawn, allowing the left atrial disk to self-expand in the left atrium, the waist to expand within the defect, and the right atrial disk to expand in the right atrium. Echocardiography was used to confirm the position of the device and to assess residual shunting across the defect. (At this point in the procedure, the device can be recaptured and repositioned if necessary.) Once occlusion was assured, the cable was unscrewed from the right disk and withdrawn with the sheath.

Patients were discharged that evening or were kept in the hospital overnight. A chest x-ray film and transthoracic echocardiogram were obtained before patients were discharged, and daily aspirin and endocarditis prophylaxis for six months were prescribed. Patients were seen for chest x-ray examination about two weeks postoperatively and again at six weeks postoperatively. At six months postoperatively, patients were seen for transthoracic echocardiography. Further follow-up was conducted by the referring cardiologist.

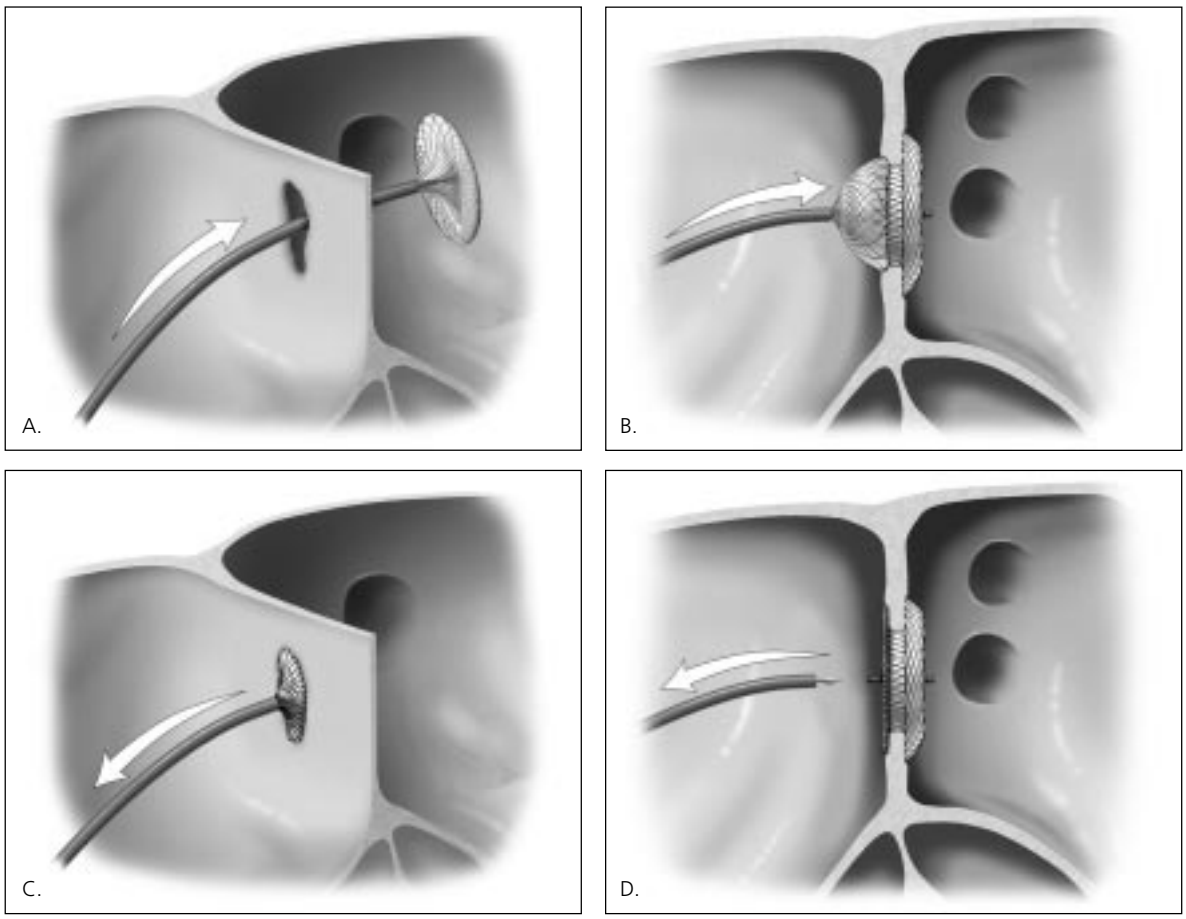
Results

Forty female and 11 male patients (age range 2 years to 69 years) were admitted to the hospital for implantation of the AMPLATZER device. Six patients were younger than five years of age, and 24 patients were younger than 21 years of age. Mean procedure time for the entire group was 68 minutes (range 24 to 138 minutes). Mean fluoroscopy time was 18.6 minutes (range 3 to 52 minutes). Thirty-nine devices were implanted in 38 patients. Device sizes ranged from 4 mm to 38 mm; 30 devices had a diameter between 10 mm and 30 mm. One complication was observed: A 53-year-old woman had hemopericardial effusion after successful deployment of the AMPLATZER device.

Thirteen of the 51 patients had no implantation of the device. In eight of these 13 patients, complex lesions or excessively large defects precluded deployment of the device; in the other five patients, the device was withdrawn after attempted deployment, either because the defect was too large or because the device could not be safely positioned. Complete closure of the defect was defined as absence of any shunt across the defect, as determined by echocardiography done at the end of the procedure or before the patient was discharged from the hospital.

In 2002, 19 patients were brought to the KP Southern California Regional Cardiac Catheterization

Figure 1. Schematic diagrams show implantation of the AMPLATZER Septal Occluder device



A: Left-side disk is delivered, via sheath, through atrial septal defect into left atrium. Disk is shown expanded. B: Right-side disk is withdrawn into right atrium. Disk is shown expanded, with waist stenting the defect. C: Securing disks are positioned against rim of defect. D: Delivery cable is released from right-side disk, with disks completely occluding defect. (Illustrations are reproduced by permission of AGA Medical Corporation and remain their sole property.)

Laboratory for closure of an atrial septal defect using the AMPLATZER device. Deployment of the device was not attempted in five (26%) of these 19 patients and was attempted in 14 (74%) of the 19 patients. Among these 14 patients, deployment was successful in 10 (71%) and resulted in complete closure. Complete closure using the AMPLATZER device was thus accomplished in 10 (53%) of our first 19 patients for whom deployment of the device was intended.

In 2003, 32 patients with atrial septal defects were brought to the Regional Cardiac Catheterization Laboratory for deployment of the AMPLATZER device. Deployment was not attempted in two (6%) of these 32 patients and thus was attempted in 30 (94%) of the 32 patients. Among these 30 patients, deployment was successful in 28 (93%) and resulted in complete closure. Complete closure using the AMPLATZER device was thus accomplished in 28 (88%) of the 32 patients for whom deployment of the device was intended.

Discussion

The advantages of the AMPLATZER Septal Occluder device include durable construction; a simple placement technique; use of small introducing sheaths; a self-centering mechanism that maximizes closure of the defect and minimizes the likelihood of device movement and embolization; usefulness for closing larger defects; and ability to be withdrawn or repositioned before its release. In our Southern California Region, introduction of new technology has of-

ten been a result of individual physician initiative, an example of which is the initiative shown for timely, successful introduction of transcatheter closure of secundum atrial septal defects. Collaboration between cardiologists in our adult and pediatric departments also was required, as was the support given by our cardiac surgeons and anesthesiologists.

To evaluate our performance, we reviewed published outcomes, starting with "intent-to-treat" data. The latter are influenced by selection criteria and by the experience of those conducting the intervention. The percentage of previously described patients for whom AMPLATZER device implantation was intended but, for various reasons, was not deployed ranged from 3.0% to 43.5%.[2-5] Our rate for this measure in 2002 was 26% and decreased to 6% in 2003. We believe that this result represents substantial improvement achieved with increased experience and was a good outcome.

The diagnosis of secundum atrial septal defects is often not made until older childhood or adulthood …

The definition of "successful closure" in the device literature varies from absence of a shunt (ie, complete closure; this is the definition we used) to presence of a residual, trivial, or small shunt. Citing results of 17 reports, Harper et al[6] concluded that "in the order of 98%" of defects in patients are closed completely by 12 months after successful deployment of the AMPLATZER device. A large, prelicensure FDA study[2] reported technical failure in only 4.3% of attempted deployments; by our calculation, their closure rate in patients who had successful deployment (including patients with small residual shunts) was 98.8% at 12 months and was 90.8% among patients for whom deployment was initially intended. Our technical results thus show substantial improvement in results for this deployment and are comparable to those published in the FDA study.

The FDA study[2] reported 7 major complications and 27 minor complications among the 442 patients treated with AMPLATZER device implantation. No deaths have been observed. Only one complication was observed in our series of patients. Concerns about future endocarditis, nickel-related toxicity, and harm from excessive fluoroscopy have been mentioned, but these possible complications are believed to be remote. However, long-term follow-up is not yet available. In the FDA study,[2] mean fluoroscopy time was 20.7 minutes (range 3.3 minutes to 75.5 minutes); mean fluoroscopy time in our study was 18.6 minutes. The FDA mean procedure time was 105.7 minutes,[2] whereas mean procedure time in our study was 68 minutes.

Clinical Implications

The diagnosis of secundum atrial septal defects is often not made until older childhood or adulthood; and life expectancy in untreated adults with these defects begins to decline substantially between ages 40 and 50 years. Surgery has greatly improved this poor prognosis and has been shown superior to medical treatment, even in highly symptomatic older adults. The high success rate and low complication rate in patients treated with the AMPLATZER Septal Occluder device have important clinical implications for management of pediatric and adult patients with secundum atrial septal defects. According to the AMPLATZER manufacturer, approximately 30,000 of these devices have already been implanted worldwide.[7] The percentage of unselected patients of all ages with secundum defects who are candidates for device closure has been estimated variously as 37%,[3] 50%,[5] or 83%.[8]

In the FDA study,[2] defect closure using the AMPLATZER device was compared with surgical closure of secundum atrial septal defects in children and adults; and the report concluded that the device is a safe, effective alternative to surgery. Advantages of the device included a much lower complication rate than surgery, avoidance of thoracotomy and cardiopulmonary bypass (which may cause cognitive impairment in adults and possibly in children), and many other obvious advantages of a nonoperative procedure, both to patients and to their families.

A clear implication drawn from our results is that for most pediatric and adult patients with secundum defects and major left-to-right atrial shunts who meet inclusion and exclusion criteria, transcatheter closure with the AMPLATZER device is preferable to surgery. Occasionally, closure of the defect is required in an infant or young child with a large left-to-right shunt or growth failure. Vogel et al[9] concluded that for patients younger than two years, the success rate with the AMPLATZER device is lower and the procedure time longer than in older patients; this observation suggests that surgery may be preferable for this younger age group. Secundum defects diagnosed in patients younger than two years and which have a diameter less than 6 mm frequently close spontaneously.[10-11] Therefore, we would agree with Harper at al[6] that if the child is asymptomatic and is growing normally, treatment should be postponed until the child is older; and that if the shunt is then clinically significant and all implantation criteria are met, closure should be attempted using the AMPLATZER device.

Conclusion

Transcatheter closure of secundum atrial septal defects for pediatric and adult patients with this very common congenital cardiac anomaly is a major therapeutic advance and is now readily available to patients in the KP Southern California Region. Use of this technology in our Region is one example of how acquisition of new technology has been facilitated by the initiative of Permanente physicians and by their commitment to evaluate critically the clinical outcomes of using new procedures. ❖

Acknowledgments

We wish to thank the Cardiac Catheterization Laboratory and Cardiac Anesthesia staffs for their dedication and skills; Farhouch Berdjis, MD, Children's Hospital of Orange County, who proctored our first cases; and Jean Losay, MD, Marie Lannelongue Hospital, Paris, France, who introduced Dr R Rosengart to the AMPLATZER device in 1999.

References

1. 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 Dec;42(4):388-93.
2. 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 Jun 5;39(11):1836-44.
3. Rastegari M, Redington AN, Sullivan ID. Influence of the introduction of Amplatzer device on the interventional closure of defects within the oval fossa in children. Cardiol Young 2001 Sep;11(5):521-5.
4. 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 Jul 16;42(2):241-5.
5. 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 Oct;118(4):674-8; discussion 678-80.
6. Harper RW, Mottram PM, McGaw DJ. Closure of secundum atrial septal defects with the Amplatzer septal occluder device: techniques and problems. Catheter Cardiovasc Interv 2002 Dec;57(4):508-24.
7. Gougeon F. In the news at AGA Medical. The Amplatzer® Focal Points Quarterly 2002 Jul:1.
8. Fischer G, Kramer HH, Stieh J, Harding P, Jung O. Transcatheter closure of secundum atrial septal defects with the new self-centering Amplatzer septal occluder. Eur Heart J 1999 Apr;20(7):541-9.
9. Vogel M, Berger F, Dahnert I, Ewert P, Lange PE. Treatment of atrial septal defects in symptomatic children aged less than 2 years of age using the Amplatzer septal occluder. Cardiol Young 2000 Sep;10(5):534-7.
10. Helgason H, Jonsdottir G. Spontaneous closure of atrial septal defects. Pediatr Cardiol 1999 May-Jun;20(3):195-9.
11. Radzik D, Davignon A, van Doesburg N, Fournier A, Marchand T, Ducharme G. Predictive factors for spontaneous closure of atrial septal defects diagnosed in the first 3 months of life. J Am Coll Cardiol 1993 Sep;22(3):851-3.

Use of this technology in our Region is one example of how acquisition of new technology has been facilitated by the initiative of Permanente physicians …

The Heart and Mind

To understand the heart and mind of a person, look not at what he has already achieved, but at what he aspires to.

— Kahlil Gibran, 1883-1931, mystic, poet, and artist