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ORIGINAL ARTICLE

Cribriform Amplatzer Device Closure of Fenestrated Atrial Septal Defects: Feasibility and Technical Aspects

Mohammed Numan · Amal El Sisi · Magdi Tofeig · Salwa Gendi · Tohami Tohami · Howaida G. El-Said

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Abstract Fenestrated atrial septal defects (F-ASDs) may pose a challenge to device closure; recently, a cribriform device with a minimal connecting intrawaist diameter and large, equal left- and right-sided discs has been designed to cover more than one adjacent defect. This study demonstrates the feasibility and technical aspects of closing F-ASDs using this new device. Sixteen patients between August 2003 and January 2006 were included in this study. The inclusion criterion was the presence of a F-ASD diagnosed by transesophageal echocardiography. One of the three available cribriform ASD device sizes (18, 25, or 35 mm) was implanted. Patients were followed for at least 1 year after the procedure. Thirteen patients had successful cribriform ASD device implantation (median age and weight, 12.5 years and 36 kg, respectively). Ten patients (62%) had an associated atrial septal aneurysm. The mean procedure time was 75.6 ± 28.5 min and the mean fluoroscopy time 14.8 ± 6.3 min. The RVEDD was significantly reduced, from a mean of 24.2 mm to 21.0 ($p < 0.05$). One patient developed atrial tachycardia requiring cardioversion during the procedure. There were no embolic events, heart block, or mortality. Complete closure was 10 of 13 (77 %) the next day and 12 of 13 (92%) at 6 and 12 months. We conclude that the cribriform Amplatzer device can be successfully and safely used in patients with F-ASDs. Complete closure may take up to 6 months.

Keywords Fenestrated atrial septic defect · Multiple atrial septal defect · Multiple ASD · Amplatzer septal occluder · Cribriform ASD device closure

M. Numan · A. El Sisi · S. Gendi · T. Tohami · H. G. El-Said
Hamad Medical Corporation, Doha, Qatar

M. Tofeig
Glenfield Hospital, Leicester, UK

H. G. El-Said
MD 3020 Children's Way, MC-5004,
San Diego 92123, California, USA

H. G. El-Said (✉)
Cairo University, Cairo, Egypt
e-mail: hgelsaid@yahoo.com

Atrial septal defect (ASD) accounts for 5%–10% of congenital heart malformations. Transcatheter closure of secundum ASD has become an alternative to surgery and the results have been mostly satisfactory. Several devices have been developed for this purpose, including the double umbrella device, buttoned device, CardioSEAL, Helex, and Amplatzer septal occluder [4, 10, 19, 24, 26–28, 32]. Large-diameter defects, multiple defects, and interatrial aneurysm with fenestrations may pose a problem to device closure [2, 21, 22, 24]. Percutaneous placement of multiple devices [23–26] or a single device after performing a balloon atrial septostomy may be required [7]. AGA Medical Corp. has recently developed the cribriform Amplatzer device, which is designed with a minimal connecting intrawaist diameter and large equal left and right discs to cover more than one adjacent defect. This study, in a cohort of patients with fenestrated ASDs (F-ASDs), reports and defines our initial experience.

Methods

Between August 2003 and January 2006, between two medical centers (Hamad Medical Center in Qatar and Cairo University in Egypt), 16 patients were diagnosed with

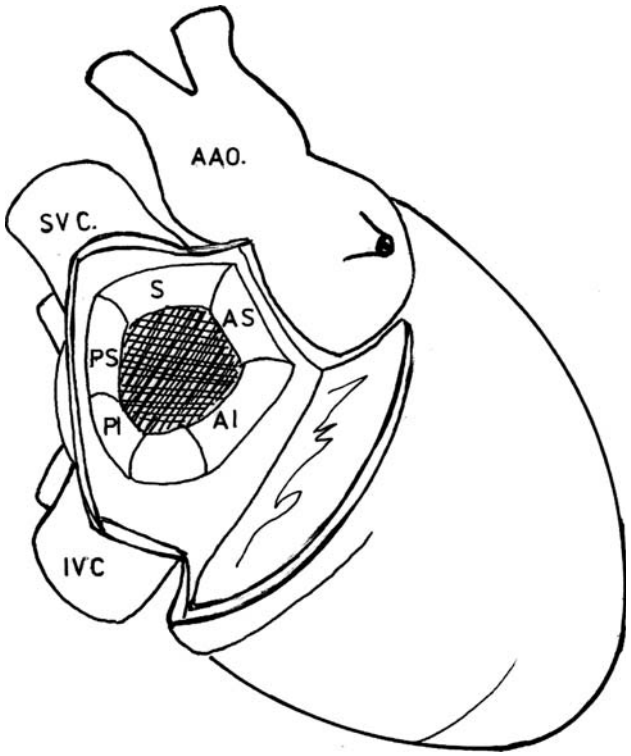

Fig. 1 Artist's drawing of right anterior surface of heart with right atrial free wall removed. Approximate locations of five measured atrial septal defect rims are labeled. AAO, ascending aorta; AI, anteroinferior; AS, anterosuperior; IVC, inferior vena cava; PI, posteroinferior; PS, posterosuperior; S, superior; SVC, superior vena cava. Courtesy of David Bichell, M.D. (From Mathewson JW, Bichell D, Rothman A, Ing F [200x] Absent posterior inferior and anterior superior atrial septal defect rims: factors affecting non-surgical closure of large secundum defects using the Amplatzer occluder. J Am Soc Echocardiogr 17(1):62–69)

F-ASD by transthoracic echo (TTE) and referred for transcatheter closure.

Cribriform Device Implantation Procedure

The procedure was done under general anesthesia. Transesophageal echocardiogram (TEE) was performed for assessment prior to and guidance during device placement. The following measurements were obtained.

- The number of defects, their size, and the distance between them were recorded.
- The "steady rim": Since the Cribriform device relies on the discs themselves to cover the defects, and not on the waist as does the regular ASD device, a new measurement had to be considered—the steady rim, which is defined as the area of the atrial septum, which includes all the openings and the aneurysm if present and is solid enough to support the device (Fig. 2b).

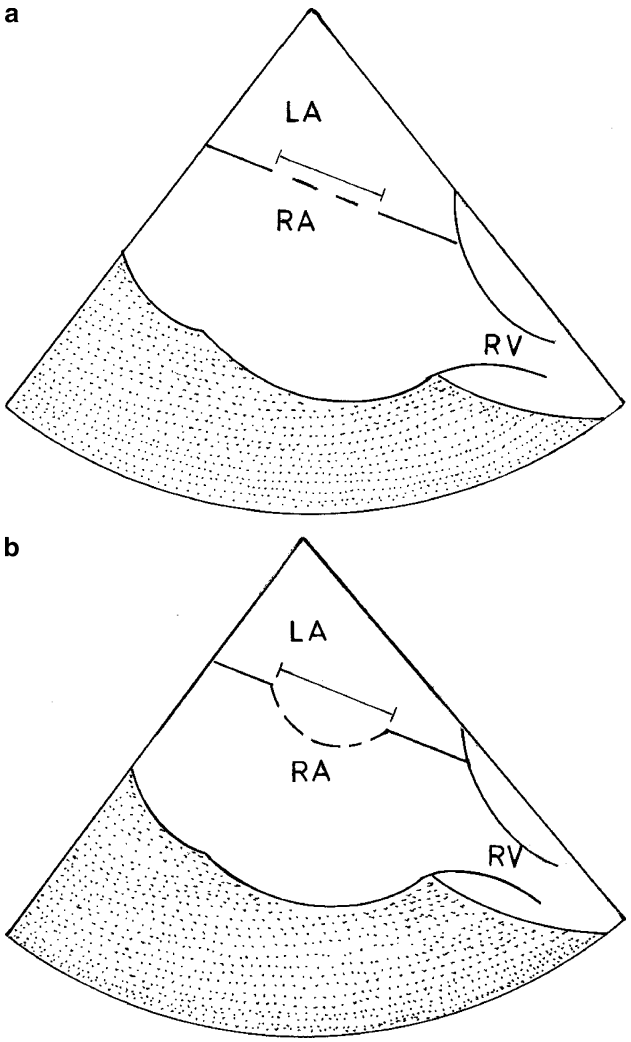

Fig. 2 Artist's drawing of transesophageal echocardiographic four-chamber view demonstrating the fenestrated atrial septal defect and sizing measurements. **a** Image of a fenestrated ASD with an aenurysm demonstrating the steady rim, which is the base of the aneurysm. **b** Image of a fenestrated ASD without an aneurysm demonstrating the steady rim measured from the superior edge of the superiormost defect to the lower edge of the inferiormost defect

- Standard rims including superior (adjacent to the superior vena cava; SVC), anterior superior (retroaortic), anterior inferior (next to the mitral valve), posterior inferior (next to the inferior vena cava; IVC), and posterior superior (adjacent to the pulmonary veins): These are described in detail by Mathewson et al. (see Fig. 1). The measurement starts from the edge of the steady rim.
- In the presence of an aneurysm that includes all the openings, the base of the aneurysm is considered the steady rim (Fig. 2a).
- Total septal length was measured in two perpendicular planes (four chamber and bicaval views).

Table 1 Demographics of patients and details of catheterization

Case no.	Wt (kg)	# of holes	Diam of largest hole (mm)	SR (mm)	TSL (mm)	Aneurysm	Hole	Cribriform device size (mm)	Residual shunt	Residual shunt, 6 m	Standard Amplatzer device (mm)
1	45	3	4.7	16	28	Y	L	25	1	N	
2	32	2	4	16	28	Y	U	25	N	N	
3	45	2	11	23	39	N	L	35	1	1	
4	24	3	5.2	20	32	Y	L	25	N	N	
5	15	>3	4.1	16	31	Y	M	25	N	N	
6	69	>3	9.6	25	39	Y	U	35	1	N	
7	30	>3	8.4	19	30	N	M	25	N	N	
8	40	>3	4	14	32	Y	L	25	N	N	
9*	13	2	12	16	27	N	M	Tried 18			16 S
10	95	3	5.7	30	46	Y	U	35	N	N	
11*	85	2	16	31	47	N	M	Tried 35			36 S
12*	15	2	11	22	40	Y	L	Tried 25			14 S
13	65	2	4.8	24	45	Y	M	35	N	N	
14	13	>3	5	22	30	N	M	25	N	N	
15	56	2	8	28	47	Y	L	35	N	N	
16	67	2	4	15	38	N	U	18	N	N	

Note. ASD, atrial septal defect; diam, diameter; S, standard ASD septal occluder implanted; SR, steady rim; TSL, total septal length; Y, yes; N, no; L, lower; U, upper; M, middle. *Failed case

- Device size selection was based on the steady rim and the total septal length measured. The device was 1.4 times the size of the steady rim or >5.5 mm larger than it. This measurement had to be shorter than the total septal length. Given that there are only three device sizes—18, 25, and 35 mm—approximation had to be done with both the steady rim and the total septal length in mind.

Once the device size was selected, the appropriate-size short sheath was placed in the femoral vein and a hemodynamic study was performed. A PVR of <4 Woods units was used as the cutoff for safety of closure. The technique of device implantation was similar to those previously described [20, 22, 35]. Fifty units of heparin and 25 mg/kg cefazoline were administered. The device position was evaluated by TEE. The presence of septal tissue "sandwiched" between both discs in multiple planes was evaluated. Clearance of the SVC, right upper pulmonary vein, and mitral valve was noted. The device was then released. The position of the device on the septum and its stability and presence of residual shunts were evaluated by TEE. Three additional doses of antibiotics were given. The following day, chest x-ray, ECG, and TTE were performed. Patients received low-dose aspirin for 6 months. TTE was performed at 1-day, 6-month, and 12-month follow-up. Residual shunt was graded as trivial if the jet width was <1 mm, small if the jet width was between 1 and 2 mm, moderate if >2 mm, and large if >4 mm [35].

Results

Between August 2003 and January 2006, 16 patients (11 females and 5 males) were referred for cribriform ASD device closure. The median age was 12.5 years (range, 3–65 years) and the median weight was 26 kg (13–95 kg). Of the 16 patients, 10 were symptomatic (66%); dyspnea on exertion was the most common symptom. One patient had a history of arrhythmias in the form of atrial fibrillation, and two patients had previous transient ischemic attacks. Two patients had mild pulmonary hypertension but normal pulmonary vascular resistance. One 7-year-old child with Down syndrome had three-fourths systemic pulmonary pressure and high PVR, which dropped to 4 Woods units on 100% oxygen, thus fulfilling the criterion for ASD closure. All the referrals were based on the TTE finding of multiple defects with or without an aneurysm of the interatrial septum (AIAS). Ten patients (62%) had an AIAS. Eight patients had two defects, three patients had three defects, and five patients had more than three defects. There were eight patients who were found to have more defects by TEE than TTE. TEE accurately assessed the measurements stated under Methods: number and size of defects, intradefect distance, standard ASD rims, steady rim, total atrial septal length, and presence or absence of an aneurysm (Table 1).

The mean procedure time was 75.6 ± 28.5 min and the mean fluoroscopy time was 14.8 ± 6.3 min. Successful

cribriform device implantation was achieved in 13 of 16 patients. Three were changed to a regular ASD device after failed attempts with the cribriform device. No patient was excluded because of rim deficiency. The mean Qp:Qs was 1.47 ± 0.3:1. Follow-up echocardiography ranged from 1 to 20 months, with a median duration of 14 months. The RVEDD was significantly reduced, from a mean of 24.2 mm prior to implantation to 21.0 mm after device placement ($p < 0.05$). One patient with Down syndrome continued to have pulmonary hypertension, RV dilatation, and severe TR after device placement. One patient, during a follow-up echocardiogram, was noted to have inadequate position of the device (lack of sandwiching of the septum at the retro-aortic rim). TEE showed no residual shunting or encroachment on the aortic valve and the device was left in place.

Table 1 details the devices deployed and the characteristics of the F-ASD in each patient. The size of the device was 18 mm in one patient, 25 mm in seven patients, and 35 mm in five patients. The largest device, 35 mm, was deployed in four adult patients. The total length of the septum was 4–11 mm longer than the device size. The device was 1.4 times the size of the steady rim or >5.5 mm larger than it. This was to ensure closure of all defects and to enclose the aneurysm, if present, and align it with the interatrial septum. Before deployment, the device was almost always at a steep angle to the septum, ~60°, with left-to-right shunting. There was significant adjusting of the device (a jump) with resolution of the shunt following release from the device cable.

Three Unsuccessful Cases

The first patient (No. 9; Table 1) was 6 years old and had two defects, the largest measuring 12 mm, with a steady rim of 16 mm, total septal length of 27 mm, and no aneurysm. An 18-mm cribriform device was implanted but the membrane tore and a regular 16-mm device was placed with no residual shunt. The second patient (No. 11; Table 1) was 65 years of age and had two defects, the largest measuring 16 mm, with a steady rim measuring 30 mm and no aneurysm. A 35-mm cribriform device was placed but kept pulling through, so it was changed for a 36-mm regular ASD device, occluding the second opening by compression of the membrane. The third patient (No. 12; Table 1) was 6 years old and had two defects, the largest measuring 11 mm, with a steady rim of 22 mm and an aneurysm. A 25-mm device was placed but pulled through easily so was changed for a standard 14-mm ASD Amplatzer occluder device.

Residual Leak on Follow-up

There was residual leak in three patients on echocardiographic examination the following day. This leak disappeared in two patients within 1 month and one patient continued to have a hemodynamically insignificant leak at 6 months. Thus complete closure was achieved immediately in 10 patients (77%), at 1 month in 11 patients (85%), and at 6 months in 12 patients (92%).

Complications

One patient developed atrial tachycardia requiring cardioversion at the time of device placement. There were no early complications such as cardiac tamponade, compromise of intracardiac structures, or device embolization. The late complications included first-degree heart block in one patient. The Down syndrome patient developed increased pulmonary hypertension and dilatation of the RV with severe TR. There were no other late complications such as infective endocarditis, thrombosis, or encroachment on intracardiac structures.

Discussion

Although surgical repair of ASD is regarded as a safe procedure, complications have been reported, including pericardial effusion, pleural effusion, and arrhythmia [12, 17, 18, 30, 33]. Additional problems include scar formation, the possible risks of blood transfusion, and postoperative chest discomfort. A recent report has shown that the mean IQ in postoperative ASD patients is slightly lower than in those who had transcatheter closure [34]. Right ventricular function could be impaired by cardiopulmonary bypass but preserved after device closure [13]. These complications can be avoided if the ASD is closed nonsurgically. The initial and intermediate-term results of transcatheter closure of ASDs are satisfactory with most devices. However, device deformities, residual shunt, distal migration, and failure of deployment have been reported, mostly with older versions of these devices [2, 4, 6, 7, 9, 10, 19–24, 26–28, 32, 35]. Serious complications, including perforation of atria, atrioventricular valve damage, and mortalities, have been reported with larger devices, which are often needed for F-ASD [2, 5, 8, 11, 14, 21–23, 25, 26, 29]. The Amplatzer ASD device occluder has recently gained wide acceptance because of its ease of deployment, retrievability before release, short procedure time, low complication rate, high success rate, and high complete occlusion rate [8, 14, 16, 20, 35].

Reported Solutions for F-ASDs

F-ASDs have been tackled in three ways. The first is percutaneous placement of two Amplatzer septal occluder devices [6, 23], which requires that the distance between the defects be >7 mm, with deployment of the smaller first device to be overlapped by the larger. The drawback of this technique is that there are no data on endothelization of two devices when overlapping. The second method is placement of a single device after performing a balloon atrial septostomy [7]. This seems very hazardous and creates a larger hole which is not regularly elliptical in shape, and thus balloon sizing becomes unpredictable (over- and undersizing). The third method was reported by Szkutnik et al. [31]. In a cohort of 41 patients with F-ASDs, a single regular ASD device was placed in 39. The investigators sized and closed only the larger defect. They concluded that if the distance between the two openings was >7 mm, residual leaks were observed but "tended to resolve in time" [31].

The Cribriform Amplazer Septal Occluder

An atrial septal aneurysm which is often associated with multiple fenestrated defects can be difficult to close with a single device and may need surgical referral, especially if the distance between the defects is >5 mm [18]. More often small defects, <4 mm, can be left, as they will not affect the hemodynamics, however, they will still pose the risk of paradoxical embolism and stroke [1]. Fischer et al.'s experience with 236 consecutive patients with transcatheter closure of ASDs showed a complete occlusion rate of 95.5%. Seven of the eight patients with residual shunts had either multiple defects or interatrial aneurysm [15]. In their series two cases were excluded because of interatrial aneurysm and multiple defects, and another three cases needed more than one device. Hence AGA Medical Corp. developed the cribriform device, which is characterized by the large right and left discs and the minimal interconnecting waist. The device should be positioned through the central defect or the major defect. It should also be positioned through the center of the aneurysm, if present, to be able to stent the aneurysm in between the two discs.

Device Size Selection

Since the cribriform device relies on the discs themselves, and not on the waist of the device, new considerations had to be made. The device size was determined by the "steady rim," the presence or absence of an aneurysm, and the total atrial septal length. The steady rim is considered the rim of the area of the atrial septum that includes all the openings and the aneurysm if present and is solid enough to support the device. The device chosen must be at least 5.5 mm larger than the steady rim, or a device-to-steady rim ratio of of 1.4:1 is used. This is similar to the device selection by Zanchetta et al. [36].

Table 2 Comparison of our study results with those of other series

	Szkutnik et al. [31]	Zanchetta et al. [36]	Our study
Country	Poland	Italy	Qatar/Egypt
Device type	Regular ASD	Cribriform	Cribriform
Number	41	24	16
Successful	39	24	13
Complete closure			
24 h	61%	67%	77%
1 mo	78%	79%	
3 mo	83%	83%	
6 mo			92%
1 yr	86%	92%	92%

Advantage of the Cribriform Over the ASD Device in Selected Cases

Of the 13 successful cases in our series, 9 had an aneurysm (69%). The cribriform device would seem to work better in the presence of an aneurysm. The bunched-up aneurysm between the discs would provide more tissue, which could potentially occlude the openings. Also, in the presence of an aneurysm the regular ASD would be less likely to work, as it will grip on pliable aneurysmal tissue, causing excess mobility of the device.

Delayed Complete Closure

We achieved complete closure in 10 of 13 patients (77%) in 24 h, 11 of 13 patients (85%) in 1 month, and 12 of 13 patients (92%) in 6 months and 1 year. This study is comparable with reports by Zanchetta et al., using the cribriform device [36], and Szkutnik et al., using a single standard Amplatzer ASD device [31], to close fenestrated defects (Table 2).

In conclusion, use of the cribriform Amplatzer device is safe and successful in a wide range of patients with F-ASDs. Complete closure may take up to 6 months.

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