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Percutaneous Occlusion of Cardiac Defects in Children

P. Syamasundar Rao*

Professor of Pediatrics & Medicine, Emeritus Chief of Pediatric Cardiology, UT-Houston Medical School, Houston, Texas, USA

In a previous editorial in this Journal [1] the role of balloon valvuloplasty and angioplasty in the management of children with congenital heart defects (CHDs) was reviewed. In this current presentation, percutaneous closure of cardiac septal defects will be discussed. Each of the cardiac septal defects will be discussed separately.

Atrial Septal Defect

After the description of surgical closure of atrial septal defect (ASD) in early 1950s, it rapidly became a standard treatment option for atrial defects. More recently, however, transcatheter device closure of ASD has, to a large extent, replaced surgery; this is mostly to avoid morbidity associated with sternotomy/thoracotomy and cardiopulmonary bypass, potential for post-operative complications, disfiguring effect of residual surgical scar, expense associated with surgical correction, and psychological trauma to the patients and/or the parents. Percutaneous device closure of secundum ASD become a standard of care in most institutions. The early studies of King and Mill [2,3], King et al. [4], Rashkind [5-7] and their associates paved the way for development of current transcatheter ASD device occlusion technology. Subsequently a number of ASD occluding devices have been designed and investigated, reviewed elsewhere [8,9]. By and large the devices were initially tested in animal models followed later by clinical trials in human subjects. The devices described thus far are listed in table 1.

Indications

The indications for closure of ASDs are right ventricular volume overloading by echocardiogram and/or a pulmonary/systemic flow ratio (Qp:Qs) greater than 1.5 (if the child had cardiac catheterization). Although asymptomatic at presentation, closure of moderate to large ASDs is recommended so that a) development of pulmonary vascular obstructive disease later in life is prevented, b) probability for development of supra-ventricular arrhythmias is reduced and c) development of symptoms during adolescence and adulthood is averted. Elective closure around age 4 to 5 years is recommended by most cardiologists.

Clinical trials

As mentioned, a large number of devices have been developed over the last three and one-half decades (Table 1). Clinical trials have been undertaken with a number of these devices as reviewed elsewhere [10-13] and feasibility, safety and effectiveness of these devices in occluding the ASD have been demonstrated. Some of the devices have been discontinued and others modified and redesigned [10-13]. At the present time, only two devices, namely, the Amplatzer Septal Occluder and HELEX device are approved for general clinical use by the US Food and Drug Administration (FDA). A number of other devices are in clinical trials either in the US or abroad [14] and will not be reviewed.

Amplatzer Septal Occluder is a double disk device constructed with 0.004" to 0.007" Nitinol (nickel-titanium compound) wire with shape memory. A 4 mm wide waist connects the left and right atrial disks and stents the ASD. The procedure of device implantation is reviewed elsewhere [14-16] and will not be reviewed here. Large defects, small septal rims, multiple defects and septal aneurysms require appropriate adjustments in the technique [17]. Both immediate [18] and mid-term follow-up [19] results of Amplatzer Septal Occluder appear excellent with immediate complete closure rates varying from 62% to 96% which improved to 83% to 99% at six to 12 month follow-up [19]. We undertook closure of 80 ostium secundum ASDs with this device; there was a small residual shunt in two patients at the conclusion of the procedure. These shunts disappeared at one and six month follow-up visits respectively. No residual shunts observed during a mean follow-up of 24 months.

HELEX device is constructed with a single strand super-elastic, Nitinol wire frame with ultrathin poly-tetra-fluro-ethylene (ePTFE) covering the entire length of the wire; when deployed, it forms two interconnected round disks, designed to be placed on either side of the atrial septum. The method of implantation is detailed elsewhere [20]. Multicenter clinical trial results [21] indicated successful implantation

Year of First Clinical Report	Name of the Device
1976	King and Mill's Device
1977	Hooked Rashkind Device
1983	Double-disk Rashkind Device
1990	Clamshell Occluder
1990	Buttoned Device (1st, 2nd & 3rd generation)
1991	ASDOS (ASD Occluding System)
1993	Monodisk Device
1994	Modified Rashkind PDA umbrella device
1997	Inverted Buttoned Device
1998	Das Angel Wing Device
1998	Amplatzer Septal Occluder
1998	CardioSEAL/StarFLEX Devices
2000	Buttoned Device (4th Generation)
2000	HELEX Septal occluder
2001	COD (Centering-on-demand) Buttoned device
2002	Transcatheter patch
2003	BioSTAR and BioTREK
2007	ATRIASEPT I
2008	Occlutech
2008	ATRIASEPT II
2008	Solysafe septal occluder
2010	ULTRASEPT
2010	The pfm ASD-R Device

Cardi-O-Fix Septal Occluder, Heart R Septal Occluder, LifetechScientific device (similar to Amplatzer device manufactured in China) and others that may have escaped detection by our literature search may be in development

Table 1: Devices Used for Closure Atrial Septal Defects.

***Corresponding author:** P. Syamasundar Rao, MD, Professor of Pediatrics & Medicine, 6410 Fannin Street, UTPB Suite # 425, Houston, TX 77030, USA, Tel:713-500-5738; Fax: 713-500-5751; E-mail: P.Syamasundar.Rao@uth.tmc.edu

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in 87% patients with low incidence of residual shunts (2.6% at one year follow-up) and wire frame fractures in 8% of patients. It is generally considered to be a good device for occlusion of small to medium-sized ASDs.

Complications

A few complications are reported at the time of Amplatzer device implantation and include device displacement, arrhythmias and rare cerebrovascular accidents [19]. During follow-up, erosion of the aortic wall by the Amplatzer device with development of aorta-to-left atrium [22] or aorta-to-right atrium [23] shunt was noted in some patients. Subsequent follow-up studies of large cohorts of patients [24,25] revealed device migration and erosion of aorta in 37 out of 35,000 (0.11% or 1 in 1,000) Amplatzer device implants world-wide and in 18 out of 15,900 implants (0.12% or 1 in 1,000) in the US study population. Based on the analysis of these data the Review Board and AGA Medical [25] suggested that the device erosion is related to over-sizing of the device and made a recommendation that device size >1.5 times the transesophageal or intra-cardiac echocardiographic diameter of ASD should **not** be used. A number of reports document wire frame fractures (WFF) following HELEX device implantation; a systematic study [26] of patients followed for >12 months revealed 6.4% fracture rate; predictors of WFF were large device size. Longer-term follow-up is necessary to evaluate this issue.

Summary

While a large number of devices have been designed and tested, only two devices (Amplatzer Septal Occluder and HELEX device) are approved by the FDA for general clinical use. A few other devices are undergoing clinical trials and are available only at institutions that participate in clinical trials. The Amplatzer Septal Occluder is rapidly becoming the device of choice because of ease with which the device can be implanted, retrieved and repositioned while the HELEX device may be useful for closure of small to medium-sized ASDs. Transcatheter occlusion of ostium secundum ASDs is feasible, safe and effective in the majority of patients.

Patent Foramen Ovale

Autopsy studies [27] indicate that a patent foramen ovale (PFO) is present in 27% of normal population. Similar prevalence rates were observed by transesophageal echocardiographic studies. Therefore, the PFO should be considered a normal variant. However, some cerebrovascular accidents and other systemic arterial emboli, especially in young patients are presumed to be due to paradoxical embolism through a PFO. Occlusion of such defects is proposed as an alternative to life-long anticoagulation. The first report of non-surgical transcatheter closure of such a defect was with King's device in 1976 [3]. Mills and King [3] closed an atrial defect with a 25 mm device in a 17-year-old male who had a stroke secondary to paradoxical embolism. A decade and one-half later, clamshell [28] and buttoned [29,30] devices were used to successfully occlude PFOs presumed to be the seat of paradoxical embolism. A number of other investigators, referenced elsewhere [31] have adopted the concept and technique. The PFOs are also considered to be the site of right to left shunt, causing hypoxemia as seen in the elderly subjects with platypnea-orthodeoxia syndrome [32,33] and patients who were previously treated for complex congenital cardiac anomalies [34,35], including Fontan fenestrations as well as in patients who had right ventricular infarction [36]. Decompression (Caisson's) illness [37-39] and migraine [39-41] have also been attributed to right to left shunt across PFO. However, there is varying degrees of evidence regarding the benefits of transcatheter occlusion of PFOs in some of these conditions.

The majority of the devices described in the preceding section (Table 1), as and when they became available, has been used to close PFOs. Some existing devices were modified or new devices designed to address the anatomic features of the foramen ovale and these include, Amplatzer PFO occluder, Cardia devices (PFO-Star and several of its subsequent generations), Premere occluder, Coherex Flat stent, PFx Closure System (not a device but employs monopolar radio frequency energy to effect closure of a PFO by welding the tissues of the septum primum with the septum secundum), pfm PFO-R, Solysafe PFO occluder and others. Most of these devices are in clinical trials in and/or outside the US, and to my knowledge, none are approved by FDA for general clinical use. Hence, these devices are available for use only at institutions participating in clinical trials. The method of implantation is of course different with different devices and should be mastered by the cardiologist performing the procedure. The Amplatzer cribriform device [42], which has features similar to Amplatzer PFO occluder [43], has been successfully used to occlude PFOs [44] and may be used on an off-label basis.

Patent Ductus Arteriosus

Surgical ligation of patent ductus arteriosus (PDA) has become standard practice in the treatment of PDA following its description by Gross and Hubbard in late 1930s. Surgical treatment has been shown to be safe and effective with only rare complications. However, several investigators attempted to develop less invasive, transcatheter methods to close the PDA. Porstmann et al. [45-47], Rashkind [7], Rashkind and Cuaso CC [48] and their associates were the first to describe PDA closure devices, paving the way for the development of a number of other devices for occlusion of PDA. There-afterwards a number of PDA occluding devices have been designed and investigated, reviewed elsewhere [49,50]. Most PDA devices were tested initially in animal models followed later by clinical trials in human subjects, similar to the ASD devices. The devices described to date are listed in Table 2.

Indications

The indications for closure of PDA are patients with continuous murmur suggestive of PDA with confirmation by echo-Doppler studies. Occlusion is not normally recommended in the so called "silent ductus" detected incidentally without typical auscultator features [51]. It is generally recommended that very small and small PDAs [50] without hemodynamic overload be occluded because of sub acute bacterial endocarditic risk. Medium- and large-sized PDAs should be closed to avoid further left heart volume overloading, treat congestive heart failure, if present and to avert pulmonary vascular obstructive disease later in life, in addition to eliminating the endocarditic risk.

Clinical trials

Clinical trials have been conducted with some of these devices as reviewed elsewhere [50,52,53] and feasibility, safety and effectiveness of some of these devices in occluding the PDA have been demonstrated. Some of the devices have been discontinued and others modified and redesigned [50,52,53]. At the present time, Gianturco coils [54], both free and detachable [55-57], Gianturco-Grifka Vascular Occlusion Device (GGVOD) [58] and Amplatzer duct occluder (ADO) [59] are currently available for general clinical use. A number of other devices are in clinical trials either in the US or abroad [50] and will not be reviewed.

Year of First Report	Name of the Device (Investigators)
1967	Ivalon foam plug (Porstmann et al)
1976	Dumbbell-shaped plug (Mills and King)
1979	Polyurethane foam covered single umbrella with miniature hooks (Rashkind & Cuaso)
1983	Two opposing polyurethane covered umbrellas (Rashkind PDA Occluder System)
1984, 1988	Botallo-occluder (Saveliev et al)
1986	Detachable silicone double-balloon (Warnecke et al)
1989	Conical nylon sack filled with segments of modified guide wire with a 1.5 cm long flexible wire cross bar attached to the distal end of the sack (Magal et al)
1990	Two polyurethane foam discs attached to each other with elastic thread (Sideris et al)
1990	Temperature-shape changeable, shape-memory polymer (polynorbornene) (Echigo et al)
1991	Adjustable Buttoned Device (Rao et al)
1991	Clamshell ASD device (Bridges et al)
1992	Gianturco Coil (Cambier et al)
1993	Butterfly vascular stent plug (Nazarian et al)
1993, 1996	Thermal shape-memory nickel-titanium coil (Liu et al)
1993	Duct-occlude pfm (Le et al)
1993	Cook Detachable Coil (Cambier et al)
1994	Silicone-coated balloon expandable stent (Moss et al)
1995	Conical-shaped stainless steel wire mesh (Pozza et al)
1996	Flipper Detachable Coil (Uzun et al)
1996	Gianturco-Grifka Sac (Grifka et al)
1996	Infant Buttoned Device (Sideris et al)
1996	Miniaturized duct-occluder pfm (Grabitz et al)
1997	Polyvinyl Alcohol Foam Plug mounted on titanium core pin (Grabitz et al)
1998	Amplatzer Duct-occluder (Masura et al)
1999	Folding Plug Buttoned Device (Rao et al)
2001	Wireless PDA Devices (Sideris et al)
2001	Reinforced Duct-occlude pfm (Le et al)
2001	Angulated Nitinol plug – Amplatzer (Kong et al)
2002	Swivel disk and plug occluders – Amplatzer (Thanopoulos et al)
2005	Amplatzer Vascular Plug (Hoyer)
2005	Nit-Occlud coils (Celiker et al)
2005	Inoue single-branched stent graft (Saito et al)
2008	Amplatzer duct occluder II - ADO II (Thanopoulos et al)
2008	Non-ferromagnetic Inconel MReye embolization coils (Grifka et al)
2008	Amplatzer Vascular Plug with prefilled embolization coils (Glatz et al)
2009	Self-expanding platinum-coated Nitinol device (Lertsapcharoen et al)
2009	Chinese self-expandable occluder, similar to the Amplatzer occluder (Yu et al)
2009	Amplatzer Vascular Plug II (Cho et al)
2009	Valved stent (Zhou et al)
2010	Cardio-O-Fix occluder** (Białkowski et al)
2011	Nit-Occlud PDA-R (reverse) device (Heath)

* Amplatzer muscular VSD devices and various ASD occluding devices, including, Rashkind, clamshell, buttoned, CardioSEAL, STARFlex, Amplatzer and Lifetech atrial septal occluder devices and aortic stents (covered) have been used for closure of large PDAs and are not separately tabulated.

**a self-expandable Nitinol wire-mesh device very similar to the Amplatzer device. ASD, atrial septal defect; PDA, patent ductus arteriosus; VSD, ventricular septal defect

Table 2: Devices Used to Occlude Patent Ductus Arteriosus*.

Gianturco coils are made up of stainless steel wire with thrombogenic Dacron fibers attached to them. They are now commercially available for clinical use in a variety of wire diameters, helical decimeters and lengths. The procedure of coil implantation is described elsewhere [54,60] and will not be discussed here. A number of modifications and refinements of the coil implantation procedure, including detachable coils were described, reviewed elsewhere [50] but, the author prefers to utilize conventional retrograde delivery of free 0.038-in Gianturco coils for very small PDAs [60,61]. Following implantation of free Gianturco coils, residual shunts were present in 18% patients 24 hours after the procedure which decreased to 9% at follow-up [52,53]. Residual shunts were present in 7% to 28% immediately after implantation of the detachable coils which reduced further at follow-up to 3% to 12% [52,53].

Gianturco-Grifka Vascular Occlusion Device. The GGVOD consists of a flexible nylon sac and a long occluding wire [58,62]; this device may have been a modification of Megal's nylon sac with a cross bar [63]. The GGVOD is manufactured in 3, 5, 7 and 9 mm sizes, all of which can be implanted via # 8 French sheaths. Residual shunts were present in 9% patients with GGVOD, all spontaneously closed during follow-up [58,62]. However, because of large delivery sheath required for implantation and difficulty in retrieval in case of device dislodgement, it not frequently used in clinical practice.

Amplatzer Ductal Occluder. The ADO is constructed with 0.004-in thick Nitinol wire mesh, mushroom in shape and self-expandable in design [59,64]. The aortic end is 2 mm larger than the pulmonary end; a thin retention disc located on the aortic end and is 4 mm larger than the aortic end of the device. A recessed screw is assembled into the pulmonary end for attachment to the delivery wire. The length of the device is 7 mm although the 5/4 device is only 6 mm long. Polyester fabric is sewn into the device to induce thrombosis after deployment. The device can be delivered via 6 to 8F sheaths, depending on the size of the device. Multiple sizes are available from the manufacturer. In a multicenter US trial [65], the ADO was implanted successfully in 435 of 439 (99%) patients. Complete closure by angiography was shown in 384 (76%) immediately following the procedure, which increased to 89% patients by echocardiography on the following day. Follow-up after one year demonstrated complete closure in 359 of 360 (99.7%) patients.

Complications

The complications are minimal although coil/device embolization may occur, requiring transcatheter or occasionally surgical retrieval [52,53]. Device/coil encroachment and obstructions either in the left pulmonary artery or descending aorta can occur particularly in small infants with large PDAs. Monitoring for these complications during follow-up is mandatory. Modifications of ADOs to address aortic obstruction were made, but none of these are currently available for routine clinical use [50].

Given the experience with a number of devices and methods of closure, it is prudent to individualize selection of method of closure based on the size (minimal ductal diameter) and perhaps the shape of PDA [50]. Very small PDAs, less than 1.5 mm can be successfully closed using conventional 0.038-in free Gianturco coils. Small PDA i. e., between 1.5 to 3 mm, while they may also be closed with 0.038-in Gianturco coils, we prefer ADO to avert the possibility of residual shunts. Moderate to large PDAs (> 3 mm) require devices and we now routinely employ ADOs. Conventional surgical closure [66] and video-

assisted thoracoscopic interruption of PDA [67] are the other available options. The selection of the method of closure of moderate to large PDA is largely dependent upon the availability of a particular device or method of closure at given institution at that particular time; however, most interventional pediatric cardiologists prefer ADO device closure.

Summary

There are a large number of devices that have been designed and tested; only few devices (free and detachable Gianturco coils, GGVOD and Amplatzer duct occluder) are approved for general clinical use. Several other devices are undergoing clinical trials and are available only at institutions that participate in clinical trials. At the present time ADO appears to be the most commonly used device worldwide in the closure of moderate to large PDAs. Transcatheter occlusion of PDAs is feasible, safe and effective in the majority of patients.

Ventricular Septal Defect

Transcatheter closure of ventricular septal defects (VSDs) in animal models was described by Rashkind [5] in 1975. He used hooked single-disc and double-disc devices. Subsequently Lock et al. [68] and Goldstein et al. [69] performed transcatheter closure of VSDs using Rashkind's double-umbrella and clamshell devices. O'Laughlin and Mullins [70] used Rashkind's PDA occluding system to occlude a residual ventricular septal defect in a child with complex congenital heart defect. Buttoned device [71,72] was utilized to close VSDs by Sideris and his colleagues. Amplatzer muscular VSD device was employed by Thonopoulos et al. [73] and Tofeig et al. [74] to close muscular VSDs. An 8 mm diameter detachable steel coil of was utilized by Kalra et al. [75] to occlude a small perimembranous ventricular septal defect with aneurysm of membranous septum in a 12 year old girl. Gianturco coils were used by Latiff et al. [76]. to occlude residual muscular VSDs in an infant after unsuccessful surgical closure. Catheter closure of perimembraneous ventricular septal defects using Amplatzer membranous VSD occluder was reported by Hijazi et al. [77]. The use of Wireless devices (Detachable balloon & transcatheter patch) was described by Sideris [78]. Cardio SEAL/STAR Flex devices were employed by Marshall and Perry [79] to close VSDs. Le et al. [80] applied Nit-occlud device to close the VSDs. Device closure of post myocardial infarction VSDs with Rashkind double umbrella [68] clamshell and Cardio SEAL or STAR Flex devices [81] and Amplatzer post infarct muscular VSD device [82] has also been attempted. The VSD closure devices described to date are listed in Table 3.

Indications

The indications for closure of VSDs are moderate to large defects with severe left ventricular volume overloading causing congestive heart failure or failure to thrive. Patients with large defects who are at risk for development of pulmonary vascular obstructive disease are also candidates for closure. Small VSDs do not need closure and are likely undergo spontaneous closure.

Clinical trials

The above described devices have undergone clinical trials and feasibility, safety and effectiveness of some of these devices in occluding the VSD have been demonstrated. However, at the present time, only Amplatzer muscular VSD occluder is approved by the FDA. Although the Amplatzer membranous VSD occluder was found useful, development of heart block [83] precipitated its removal from clinical trials. Cardio SEAL and STAR Flex device in the past received humanitarian device exemption (HDE) for high risk patients. Other devices are in clinical trials either in the US or abroad and will not be reviewed.

Amplatzer muscular VSD occluder. The device is made up of Nitinol wire mesh similar to Amplatzer ASD and PDA occludes and consists of two low profile disks connected to each other with a 7-mm waist. It is self-centering and repositionable, again, similar to other Amplatzer devices. The device size (measured by the diameter of the waist in mm) is selected based on the measured transesophageal echocardiograph (TEE) and/or balloon stretched VSD diameters; the selected device size is usually 1- to 2-mm larger than the size of the defect. The procedure of device occlusion of VSD is more complex than that is required for ASD or PDA closure. It involves crossing the VSD, mostly from the left ventricular side, forming an arteriovenous loop and positioning the delivery sheath in the left ventricle either from the femoral vein or jugular vein depending upon the location of the VSD. Angiographic and TEE monitoring of the device position during implantation under general anesthesia is necessary for accurate device placement. The results of closure are generally good with complete or partial closure and clinical improvement in most patients [73,74,84-89]. Complication rates are slightly higher than those observed with ASD or PDA closure. In one study [87] involving 48 muscular VSDs (mid-muscular, anterior, posterior, or apical), Amplatzer muscular VSD occluders were delivered successfully in all subjects with no residual shunt following device implantation. Transient complete heart block was observed in one patient 24 hours after the procedure and no aortic or tricuspid regurgitation. In another study [88] involving 30 muscular defects closed with Amplatzer muscular VSD occluders, similar results were recorded, although one device embolized requiring transcatheter retrieval.

Closure of post-myocardial infarction VSDs with Amplatzer postinfarct muscular VSD (PIMVSD) device is feasible [82] and will not be reviewed.

Summary

At the present time only Amplatzer muscular VSD occluder for closure of muscular VSD is approved for general clinical use in the US. Other VSD occluding devices are in clinical trial in US and elsewhere and can only be used at institutions participating in clinical trials.

Year of First Report	Name of the Device
1975	Rashkind's hooked single-disc and double-disc devices
1988	Rashkind's double umbrella device
1989	Rashkind PDA Occluder System
1990	Clamshell device
1996	CardioSEAL Device
1997	Buttoned device
1998	Self-adjustable buttoned device
1999	Amplatzer VSD occluder
1999	Detachable steel coil
1999	Gianturco coils
2002	Amplatzer membranous VSD occluder
2003	Wireless devices (detachable balloon & transcatheter patch)
2003	STARFlex device
2003	Nit-occlud device
2004	Amplatzer postinfarct muscular VSD (PIMVSD) device

PDA, patent ductus arteriosus; VSD, ventricular septal defect

Table 3: Devices Used for Closure Ventricular Septal Defects.

Aortopulmonary Window

Aortopulmonary window (APW) is a rare congenital cardiac defect with an incidence of no more than 0.1% of all congenital cardiac defects. Most of APWs require surgical closure because they are usually large and have small inferior or superior rim and are not candidates for percutaneous closure. However, intermediate defects with well formed inferior and superior rims, constituting 12% of the defects [91] may be amenable to transcatheter approach.

A number of reports [92-105], mostly single case reports of device closure of APWs document feasibility, safety and effectiveness of percutaneous intervention. Both native (previously un-operated) [92-104] and residual post-surgical [105] defects can be occluded. Several types of devices, namely, Rashkind PDA occluder, buttoned device, custom made Amplatzer closure device, Amplatzer duct occluder, Amplatzer septal occluder, Shen-Zhen Lifetech Scientific Inc's muscular ventricular septal occluder have been used in the past [92-105]. Initially, an arteriovenous guide wire loop is established by passing a guide wire from the femoral artery (via a catheter) through the APW into the pulmonary artery, the guide wire snared and brought out through the femoral vein. The delivery sheath was then positioned transvenously over the guide wire. The delivery and implantation of the selected device is similar to the implantation of the PDA devices. The results were good with minimal or no residual shunt.

The above described experience, though limited, suggests feasibility, safety and effectiveness of device closure of the APWs. It should however be noted that only a small percentage (~10%) of APWs are amenable for transcatheter closure. Accurate assessment of the size, if necessary by balloon sizing, make sure that there are adequate superior and inferior margins surrounding the defect and ensure lack of interference with critical structures (coronary artery, pulmonary artery) are important for successful use of percutaneous device placement.

Conclusion

A large variety of devices to occlude cardiac septal defects have been designed and tested in animal models followed by human clinical trials. Some devices were discontinued, many devices are in clinical trials and a few devices are approved for general clinical use. The feasibility, safety and effectiveness of device closure of septal defects are excellent. However, careful selection of patients and devices and meticulous attention to details of the technique of implantation are mandatory to achieve successful outcome. Further refinement in the devices and technique is anticipated and is expected to be beneficial to our patients.

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