

## Historical Aspects of Transcatheter Treatment of Heart Disease in Children

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### Abstract

The very first transcatheter intervention to treat congenital cardiac defects was reported by Rubio-Alvarez et al. [1] in 1953, when they performed pulmonary valvotomy using a modified ureteral catheter. A decade later Dotter, Rashkind, Porstmann and their associates described progressive dilatation of peripheral arterial stenotic lesions, balloon atrial septostomy and transcatheter occlusion of patent ductus arteriosus, respectively. The purpose of this review is to present these and other historical developments of catheter-based interventions in the treatment of heart disease in children. Historical aspects of 1. balloon angioplasty/valvuloplasty of valvar pulmonary stenosis, valvar aortic stenosis, fixed subaortic stenosis, native aortic coarctation, postsurgical aortic recoarctation, branch pulmonary artery stenosis, mitral stenosis, cyanotic heart defects with pulmonary oligemia, stenotic bioprosthetic valves, congenital tricuspid and mitral stenosis, truncal valve stenosis, subvalvar pulmonary stenosis, supra-valvar pulmonary stenosis (congenital membranous or postoperative), stenosis of the aorta (Leriche syndrome, atherosclerotic and Takayasu's arteritis), baffle obstruction following Mustard or Senning procedure (both systemic and pulmonary venous obstructions), superior and inferior vena caval obstructions, pulmonary vein stenosis, pulmonary veno-occlusive disease, vertical vein stenosis in total anomalous pulmonary venous connection, pulmonary venous obstruction following repair of total anomalous pulmonary venous obstruction, specially designed pulmonary artery bands, cor triatriatum, cor triatriatum dexter, and coronary artery stenotic lesions that develop after Kawasaki disease; 2. stents to enlarge stenotic lesions of branch pulmonary arteries, systemic veins, systemic and pulmonary venous pathways after Mustard procedure, aorta, right ventricular outflow conduits, pulmonary veins and native right ventricular outflow tract or to keep the ductus arteriosus open in patients with pulmonary atresia and hypoplastic left heart syndrome and maintaining patency of stenosed aorto-pulmonary collateral vessels, surgically created but obstructed shunts or acutely thrombosed shunts as well as covered stents; 3. transcatheter occlusion of cardiac defects comprising of atrial septal defect, patent foramen ovale, patent ductus arteriosus, ventricular septal defect and aortopulmonary window and 4. catheter-based atrial septostomy such as Rashkind balloon atrial septostomy, Park's blade atrial septostomy, balloon angioplasty of the atrial septum, trans-septal puncture and atrial septal stents were presented.

**Keywords:** Therapeutic catheterization; Historical aspects; Interventional pediatric cardiology; Balloon angioplasty/valvuloplasty; Transcatheter occlusion; Stents; Atrial septostomy; Atrial septal defect; Patent ductus arteriosus; Patent foramen ovale

### Introduction

The conventional treatment of structural heart defects has been corrective surgery. However, over the last three decades, increasing number of percutaneous, transcatheter methods have become available to address the cardiac defects. Although transcatheter method of treatment of congenital heart defects (CHDs) began in early 1950s [1,2], it is not until mid/late-1980s that a wider practice of transcatheter interventions in children was possible with the exception of balloon atrial septostomy which has been in usage since 1966 [3]. Rubio-Alvarez et al. [1] in 1953 performed pulmonary valvotomy using an ureteral catheter with a wire passed through it; the tip of the catheter was bent and the wire kept straight so that the wire could cut the fused commissures of the pulmonary valve. They have done this to emulate Brock's closed pulmonary valvotomy [4] with this procedure in a 10-month-old child, they decreased the peak-to-peak pulmonary valve gradient from 72 mmHg to 59 mmHg. While this is a modest improvement, they observed clinical improvement. To my knowledge this is the first attempt for treating CHD by transcatheter methodology. The very following year [2], they performed a similar procedure in another patient with pulmonary valve stenosis and in several patients with tricuspid valve stenosis with remarkable improvement in clinical status. No further reports of this technique either by the same investigators or others were published in the literature. Ten years later, in 1964, Dotter and Judkins [5] performed progressive dilatation of peripheral arterial stenotic lesions, beginning with passage of

guide wires across the stenotic lesion followed by increasing sizes of dilating catheters; both immediate and follow-up results were good. Later in the same decade Rashkind and Miller [3] described balloon atrial septostomy and Porstmann et al. [6] developed transcatheter occlusion of patent ductus arteriosus (PDA). These and other historical developments were reviewed in 1993 in a textbook chapter [7]. The purpose of this review paper is to further expand and update historical aspects of transcatheter treatment of heart disease in children. Assignment of historical priority is based on verifiable publications to the satisfaction of the author of this paper. The individual procedures will be discussed followed by their application to a particular cardiac defect.

### Balloon Angioplasty/Valvuloplasty

As mentioned in the introductory section, Rubio-Alvarez [1] reported the use of a modified ureteral catheter in treating pulmonary and tricuspid valve stenoses in early 1950s [2]. A decade later, Dotter

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and Judkins [5] utilized a gradational dilatation technique to recanalize stenotic and occluded peripheral arteries. In mid to late 1970s, Gruntzig and his associates [8] extended the concept of Dotter and Judkins [5] by developing a double-lumen catheter with a non-elastic balloon which they successfully used to dilate stenotic lesions of the iliac, femoral, popliteal [9], renal [10] and coronary [11,12] arteries. The use of balloon dilatation catheters was then extended to dilate and relieve obstructive lesions of the aorta [13], pulmonary valve [14], aortic valve [15], mitral valve [16] and other stenotic lesions [17,18].

### **Pulmonary stenosis**

To the best of my knowledge the first attempt to relieve pulmonary valve obstruction by transcatheter methodology was in the early 1950s by Rubio-Alvarez et al. [1,2] with the use of an ureteral catheter with a wire to cut open the stenotic pulmonary valve. Semb and his associates [19] accomplished relief of pulmonary valve obstruction by rapidly withdrawing an inflated balloon (Berman angiographic catheter) across the pulmonary valve in 1979. However, this technique was not adopted for general clinical use. Subsequently, Kan and her associates [14] adopted the techniques of Dotter and Judkins [5,20] and Gruntzig et al. [8-12] to relieve pulmonary valve obstruction by the radial forces of balloon inflation of a balloon catheter positioned across the pulmonary valve. This static balloon dilatation technique is currently employed throughout the world to relieve pulmonary valve obstruction.

The concept of use of large balloons to dilate the pulmonary valve with a balloon/annulus ratio of 1.2 to 1.4 was developed based on the immediate [21] and both immediate and follow-up [22] results. Subsequently, recommendations were made to reduce the suggested balloon/annulus ratio to 1.2 to 1.25 [23,24] based on a study [25] demonstrating development of significant pulmonary insufficiency, some requiring pulmonary valve replacement, with the use of large non-compliant balloons. We also pointed out that pulmonary insufficiency is likely to be a problem during long-term follow-up [26] and that we should be vigilant to monitor for progressive pulmonary insufficiency during late follow-up.

We were among the first to investigate causes of restenosis [27] following balloon pulmonary valvuloplasty. Based on multivariate logistic regression analysis, two risk factors for recurrence were identified: balloon/pulmonary valve annulus ratio < 1.2 and immediate post-valvuloplasty gradient  $\geq 30$  mmHg. These results were later confirmed by a large multi-institutional study [28].

### **Aortic stenosis**

Following successful application of Gruntzig's technique [8,9,12] to aortic coarctation [13] and pulmonary valve stenosis [14], Lababidi and his associates extended the technique of balloon dilatation to aortic valvar stenosis [15,29]. We were among the first to investigate the causes of recurrence of stenosis following balloon aortic valvuloplasty [30] and found that age < 3 years and immediate post-balloon aortic valve peak-to-peak gradient > 30 mmHg are predictors of restenosis and suggested that avoiding or minimizing risk factors may help reduce recurrence after valvuloplasty. We have also attempted to investigate the causes of aortic insufficiency during follow-up after balloon aortic valvuloplasty [31].

### **Fixed subaortic stenosis**

Suarez de Lezo et al. [32] reported use of balloon angioplasty for relief of obstruction caused by fixed subaortic membranous stenosis

in 1986. The data of Lababidi [33] Shrivastava [34] and their associates suggest that best results are obtained when the subaortic membrane is thin, less than 2 mm. More recently, Suarez de Lezo [35] identified subaortic membrane thinner than 2.5 mm and age  $\geq 13$  years are predictors of good outcome following balloon dilatation.

### **Native aortic coarctation**

Gruntzig's technique of balloon angioplasty was adopted by Sos et al. [13]; they performed balloon angioplasty of coarcted aortic segments in a postmortem specimen in 1979 and demonstrated that it is feasible to enlarge the coarcted aortic segments. Subsequently Singer et al. [36] in 1982 used the technique to relieve obstruction caused by post-operative aortic recoarctation. However, it is Sperling et al. [37] in 1983, who first performed balloon angioplasty of native coarctation in two infants. A number of other cardiologists applied this technique in a large number of patients both with native coarctation [38] and post-surgical recoarctation [39], reported by VACA Registry. Although there was similar relief of obstruction and similar complication (and death) rates [40], the Registry investigators [38,39] stated that "the question remains not can it be done, but should it be done?" for native coarctation [38] and "... balloon angioplasty for relief of residual or recurrent aortic coarctation offers an acceptable alternative to repeat surgical repair" for post-surgical recoarctation [39] This interpretation was questioned [40] stating that "this is not logical and that objectivity of scientific interpretation should be maintained." Subsequently, additional arguments were presented [41-43] advocating balloon angioplasty as a first-line therapeutic option in the management of native coarctation. Subsequently, a number of other centers adopted balloon angioplasty of aortic coarctation, as reviewed elsewhere [44]. Causes of recoarctation following balloon angioplasty [45], aortic remodeling after balloon angioplasty [46,47] and biophysical response of coarcted aortic segment to balloon dilatation [48] were investigated thereafter.

### **Postsurgical aortic recoarctation**

Following the application of Gruntzig's technique of balloon angioplasty by Sos et al. [13] to dilate coarcted aortic segments in a postmortem specimen in 1979, Singer et al. [36] in 1982 utilized the technique to alleviate post-operative aortic recoarctation. At the present time balloon angioplasty is preferred treatment for these recoarctations.

### **Branch pulmonary artery stenosis**

Martin et al. [17] were the first to report balloon angioplasty of branch pulmonary artery stenosis in an 18-year-old patient who developed bilateral branch pulmonary following surgical repair of tetralogy of Fallot; immediate angiographic improvement was demonstrated. Shortly thereafter, Lock and his associates [49] attempted balloon angioplasty of both right and left pulmonary arteries in seven children; the procedure could not be performed in two children because of technical difficulties. In the remaining five children, the gradient across the obstruction decreased, the diameter of the narrowed segment improved and the blood flow, estimated by quantitative pulmonary perfusion scan to the ipsilateral lung increased. Other cardiologists began using the technique, as reported in the VACA Registry [50] While there is improvement in vessel size and pressure gradient, there was only minor reduction of proximal pressures. In the best of hands and with an appropriate technique, success rate is in the

range of 50% and complication rate is high [51]. High pressure balloon angioplasty, despite initial enthusiasm [52] did not seem to produce good results. Most authorities believe placement of intravascular stents is the best method of treatment for branch pulmonary artery stenosis.

### Mitral stenosis

Transcatheter balloon mitral valvotomy for rheumatic mitral stenosis was first introduced by Inoue et al. [16] in 1984. They used a specially designed balloon with reinforced nylon micromesh; the balloon size and shape can be changed depending on the degree of inflation (which in turn is related to the amount of diluted contrast material used). The procedure was successfully performed in five of the six rheumatic mitral stenosis patients in whom it was attempted; reduction in the mean diastolic pressure gradient across the mitral valve was observed. Subsequently conventional single [53] and double [54] balloons were used with similar results. Subsequent experience, however, suggested that the Inoue balloon may be better because the operator can gradually increase the balloon size until an optimal result is achieved; this appears to be the most common method used in countries where rheumatic mitral stenosis is prevalent.

### Cyanotic heart defects with pulmonary oligemia

Following the description of balloon pulmonary valvuloplasty for isolated pulmonary valve stenosis by Kan et al. [14], we [55,56] were among the first to adopt balloon pulmonary valvuloplasty to augment pulmonary blood flow instead of systemic-to-pulmonary artery shunt and successfully relieved pulmonary oligemia and improved systemic arterial hypoxemia. Subsequently other workers employed this technique [57-61] We recommend that this procedure be performed in selected patients who need palliation of pulmonary oligemia but are not candidates for total surgical correction, valvar obstruction is a significant component of the right ventricular outflow tract obstruction and multiple obstructions in series are present [62-65]. We have demonstrated improvement in anatomy of the lesion at follow-up evaluation so that complete surgical correction could be performed at a later date [62-64].

### Stenotic bioprosthetic valves

Degenerative and calcific changes have been observed in all types of bioprosthetic valves and valve conduits, irrespective of the manufacturer [66,67]; this may lead to obstruction of the valves. These appear to occur more frequently and more rapidly in younger children than in older children and adults. Stiffening of the valve cusps as well as calcium deposits along the commissures, causing commissural fusion produce valve obstruction. Furthermore, there may be narrowing at the anastomotic sites of the conduit. Repeat surgical replacement with another prosthetic valve has been the conventional approach. Lloyd, Waldman and their associates [68,69] have independently and almost simultaneously used balloon dilatation to relieve obstructive lesions of porcine heterografts in pulmonary position. These and other studies suggest significant gradient reduction along with either avoidance or postponement of prosthetic valve replacement [67]. Balloon dilatation of bioprosthetic valves in tricuspid [70], mitral [71] and aortic [72] position has been undertaken with significant hemodynamic improvement [67]. However, balloon dilatation of left sided bioprosthetic valves has potential for dislodgment and systemic embolization of calcific debris and fractured valve leaflets. Embolic-protecting device to capture embolic material has been designed and used successfully [73].

### Other lesions

Less common stenotic lesions of the heart and great vessels treated with balloon dilatation [74] will be cited in this section and the interventionalist who first used this technique will be referenced. These obstructive lesions include, congenital tricuspid [2,75,76] and mitral [77] stenosis, truncal valve stenosis [78], subvalvar pulmonary stenosis [79,80], supravalvar pulmonary stenosis (congenital membranous [81] or postoperative [82,83]), stenosis of the aorta (Leriche syndrome [84], atherosclerotic [85] and Takayasu's arteritis [86,87]), baffle obstruction following Mustard [88] or Senning procedure [89] (both systemic [88,89] and pulmonary [90] venous obstructions), superior [91,92] and inferior [93-95] vena caval obstructions, pulmonary vein stenosis [18], pulmonary veno-occlusive disease [96], vertical vein stenosis in total anomalous pulmonary venous connection [97], pulmonary venous obstruction following repair of total anomalous pulmonary venous obstruction [74], specially designed pulmonary artery bands [98,99], cor triatriatum [100], cor triatriatum dexter [101], and coronary artery stenotic lesions that develop after Kawasaki disease [102]. These have been reviewed at greater detail elsewhere [74].

### Stents

While describing percutaneous transluminal balloon dilatation in 1964, Dotter and Judkins [103], raised the stent concept. A few years later Dotter [104] implanted spiral coil-spring device into peripheral artery stenotic lesions produced in an animal model. In early 1980s self-expanding double helical spiral stents were implanted in experimentally created vascular stenotic lesions [105]. In mid 1980s, Palmaz et al. [106] successfully implanted stainless steel mesh stents in rabbit aortae, hepato-biliary circulation and canine coronary arteries and showed the feasibility of stent concept. Human applications followed with the use of stents in the treatment of obstructive lesions of iliac [107], renal [108] and coronary [109] arteries in adult subjects. Then the stent concept was applied to pediatric patients [110]. The technique was initially employed to treat stenotic lesions of branch pulmonary arteries and systemic veins [110]. Subsequently the stent use was extended to relieve obstructions in the systemic [111] and pulmonary [112] venous pathways after Mustard procedure, aorta [113], right ventricular outflow conduits [114], pulmonary veins [115,116] and native right ventricular outflow tract [117]. Stents were also utilized to keep the ductus arteriosus open in patients with pulmonary atresia [118] and hypoplastic left heart syndrome [119] and maintaining patency of stenosed aorto-pulmonary collateral vessels [120], surgically created but obstructed shunts [121] or acutely thrombosed shunts [122]. Further modifications of stents such as covered stent (covered with polytetrafluoroethylene membrane or similar material) to treat aortic coarctation with aneurysm [123], biodegradable [124] and Growth [125] stents to address problems associated with growth of the children and drug-eluting stents [126] to prevent neo-intimal proliferation have taken place. Stents have also been utilized in hybrid procedures to complete Fontan by a staged surgical-catheter approach [127] and to stent the ductus (and PFO if necessary) along with surgical bilateral branch pulmonary artery banding in the palliation of hypoplastic left heart syndrome [128].

### Transcatheter Occlusion of Cardiac Defects

Porstmann and his associates [6] described transcatheter occlusion of patent ductus arteriosus (PDA) in 1967. Subsequently, King [129] in 1974 and Rashkind [130] in 1975 developed devices to close atrial septal defects (ASDs). The historical aspects of each of cardiac septal defects will be described separately hereunder.

## Atrial septal defect

King and Mills [129] described a device composed of paired, Dacron-covered stainless steel umbrellas collapsed into a capsule at the tip of a catheter and used it to occlude ASDs that were created by a punch biopsy technique in adult dogs. They achieved successful device deployment in five of nine dogs in whom the procedure was attempted. Complete closure of the ASD and endothelialization of the implanted umbrellas was observed during the follow-up. They then extended the technique to human subjects [131,132]. They measured stretched ASD diameter by balloon sizing [133] and employed devices 10 mm larger than the stretched ASD diameter. Eighteen patients were evaluated in the catheterization laboratory and ten (56%) patients were found suitable for device closure. Of these, five (50%) patients had successful implantation of the device. Cardiac catheterization data did not show shunts by oximetry.

Rashkind [130,134] developed a slightly different type of ASD closure device; the first Rashkind umbrella consisted of three stainless-steel arms covered with foam which was subsequently modified such that there are six stainless steel arms with the alternate arms carrying a miniature "fish" hook. The central ends of the stainless-steel arms are attached to miniature springs, which in turn are welded to a small central hub. An elaborate centering mechanism, consisting of five arms bent to produce a gentle outward curve was also incorporated into the device delivery system. The delivery mechanism is built on a 6 F catheter with locking tip, which interlocks with the central hub of the device. The umbrella collapsed into a pod and the folded centering mechanism can be loaded into a 14 or 16 F long sheath. A device that is approximately twice the stretched size of the ASD was chosen for implantation. Surgically created ASDs in dogs and calves were closed with the device and these experiments have indicated the feasibility of the method and excellent endothelialization of the umbrella components. Studies in human subjects followed [134,135]; of 33 patients recruited for clinical trials, device implantation was not attempted in 10 patients because the ASD was too large or too small. In the remaining 23 patients, 14 (61%) had adequate ASD closure and in nine (39%) the results were considered unsatisfactory. Because of identified problems, Rashkind modified this device into a double disc prosthesis [135] which was patterned after a patent ductus arteriosus occluding device [136] that he was concurrently developing.

Because of the inability of the umbrellas to fold back against each other, Lock et al. [137] modified the device by introducing a second spring in center of the arms and the modified device was named clamshell occluder; this was successfully implanted in six of eight lambs. The clamshell device implantation was extended to human subjects [138]; seventeen devices were implanted with no residual shunts in the majority of patients both immediately and six month after device placement. Hellenbrand et al. [139] also used of this device and were among the first to advocate transesophageal echocardiographic (TEE) monitoring during the procedure. Clinical trials by these and other investigators continued but because of fractures of the arms of the device in 40 to 84% of devices with occasional embolization [140,141], further clinical trials with the device were suspended in 1991 by the FDA and the investigators.

Subsequently a number of other devices were described and these include: original buttoned device [142,143], ASDOS (atrial septal defect occluding system) [144], second and third generation buttoned

devices [145,146], monodisk device [147], Das Angel Wing Device [148], centering buttoned device [149], inverted buttoned device to address closure of right to left shunts [150], Amplatzer septal occluder [151,152], CardioSEAL device [153], STARFlex device [154], fourth generation buttoned device [155,156], Sideris' Wire-less devices including transcatheter patch [157,158], HELEX septal occluder [159,160], centering on demand buttoned device to center the device in the ASD when required [161], fenestrated Amplatzer device to keep atrial septal defects open to maintain cardiac output [162], hybrid buttoned device to address closure of defects with associated with atrial septal aneurysm [163], cribriform device to occlude multiple or fenestrated ASDs [164], BioSTAR [165,166], nanoplatinum coating to prevents nickel release from Amplatzer devices, thus averting Kounis syndrome [167], Solysafe Septal Occluder device [168], BioTREK [169], Occlutech [170], ATRIASEPT I-ASD device [171], ATRIASEPT II-ASD and ULTRASEPT [172], The pfm ASD-R devices [173] and others. Other devices such as Cardi-O-Fix Septal Occluder, Heart R Septal Occluder, cocoon, LifetechScientific device (also called sears device), some manufactured in China and others that may have escaped detection by our literature search and may be in development. Despite extensive studies with many of these devices, Amplatzer Septal Occluder and HELEX are the only two devices that are approved for general clinical use by the FDA. A number of other devices are in clinical trials either in the US or in other countries. The interested reader referred elsewhere [7,174-176] for a more detailed discussion of historical aspects of ASD closure devices.

## Patent foramen ovale

While a patent foramen ovale (PFO) is present in 27% of normal population and should be considered a normal variant, shunting across it is presumed to be causing: 1) cerebrovascular accidents, especially in young patients, 2) hypoxemia in the elderly subjects with platypnea-orthodeoxia syndrome, 3) cyanosis in patients who were previously treated for complex congenital cardiac anomalies, 4) arterial oxygen desaturation in patients who had right ventricular infarction, 5) decompression (Caisson's) illness and 6) migraine. The first report of transcatheter closure of such a defect was with King's device in 1976 [131]; Mills and King closed an atrial defect with a 25 mm device in a 17-year-old male who had a stroke secondary to paradoxical embolism. Subsequently, clamshell [177] and buttoned [145,178] devices were used to occlude PFOs. Other investigators, referenced elsewhere [179] have adopted the concept and technique. Vast majority of the devices described in the ASD section, as and when they became available, were used to close PFOs. Existing ASD closure devices were modified or new devices designed to address the anatomic features of the foramen ovale and these include, Amplatzer PFO occluder [180], Cardia devices (PFO-Star and several of its subsequent generations) [172,181], Premere occluder [182], Occlutech septal occluder [183], Coherex Flat stent [184], pfm PFO-R [173], Solysafe PFO occluder [168] and others. Some of these devices are in clinical trials in and/or outside the US, and none are currently approved by FDA for general clinical use. The Amplatzer cribriform device [185], which has features similar to Amplatzer PFO occluder [180], has been successfully used on an off-label basis to occlude PFOs [186].

## Patent ductus arteriosus

Porstmann and his associates [6,187,188] were the first to describe a PDA closure device, paving the way for the development of a number of other devices for occlusion of PDA. Porstmann's device consisted

of conical-shaped Ivalon foam plastic plug, custom-made based on the shape and size of the ductus seen on lateral view of an aortogram. A guide wire (0.04 mm) loop from the femoral artery, aorta, ductus, pulmonary artery, right ventricle, right atrium, inferior vena cava to the femoral vein was first established and the Ivalon plug was introduced over the guide wire already in place into the femoral artery with the help of a tubular applicator. The plug was advanced with a catheter, still over the guide wire, and forced into the aortic ampulla of the PDA. After confirmation of good position of the prosthesis within the ductus, the guide wire loop was removed from the femoral vein. Experimentation in animal models was undertaken initially to develop and refine the method. In their first series of 62 patients, successful closure was accomplished in 90% patients. It was not technically feasible to implant the Ivalon plug in the remaining 6 (10%) patients. During a follow-up period up to 4.5 years, no recurrences were noted [188].

A number of other devices were subsequently designed and tested in animal models, but did not reach the stage of human clinical trials and these include, dumbbell-shaped plug [131], cylindrical Ivalon sponge plug tied securely to a stainless steel umbrella detachable silicone double-balloon, 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, temperature-shape changeable, shape-memory polymer (polynorbornene), butterfly vascular stent plug, conical-shaped stainless steel wire mesh, thermal shape-memory nickel-titanium coil, miniaturized duct-occluder pfm, double-cone shaped, stainless steel coils with enhanced stiffness of the outer rings and Valved stent and these devices were described and referenced elsewhere [189-191].

Rashkind [135,192] devised a single polyurethane foam-covered umbrella with miniature hooks (fish hooks) to occlude the PDA. The umbrella is attached to the delivery system by a simple eye pin and sleeve mechanism. The device, loaded into a 6F sheath, is introduced via the femoral artery and implanted across the ductus retrogradely. The success rate was 100% in experimental calf model. Among twenty patients in whom the device implantation was attempted, it was implanted successfully in 17 (85%) patients. Complete closure was demonstrated in eight (47%) of the 17 patients. Because of multiple problems with the hooked device, Rashkind redesigned the system into a double-disc, non-hooked device [136]. The device is made up of two opposing polyurethane foam disc umbrellas (three stainless steel arms) attached to a central spring mechanism. The device is delivered into the ductus transvenously in contradistinction to transarterial device delivery required with Porstmann's Ivalon plug and Rashkind's single-disc hooked device. Testing in animal models in 19 calves and swine revealed successful implantation in all [135]. In the initial clinical experience [135] with eight patients, three (38%) PDAs were too large to attempt closure, four (50%) had successful closures and one (13%) had incomplete closure. In a multicenter FDA trial organized by Rashkind [136], successful closure was observed in 94 (64%) of 146 patients. Device embolized in 19 (15%) with significant residual shunts in 15 (10%). Subsequently clinical trials by these and other investigators showed somewhat improved results with experience, but the device never received FDA approval.

Subsequently a number of other devices were described and these include: botallooccluder [193], buttoned device [194-196], clamshell septal umbrella [197], Gianturco coil [198], Duct Occlud pfm [199], detachable (Cook and Flipper) Coils [200-202], Gianturco-Grifka vascular occlusion device (GGVOD) [203], polyvinyl alcohol (Ivalon R) foam plug [204], infant buttoned device [205,206], Amplatzer duct

occluder [207,208], folding plug buttoned device [209], wireless PDA devices [210,211], reinforced duct-occlude pfm [212], Amplatzer muscular ventricular septal defect occluder [213], Amplatzer vascular plug [214], Nit-Occlud coils [215], Inoue single-branched stent graft [216], non-ferromagnetic Inconel MR eye embolization coils [217], Amplatzer vascular plug with prefilled embolization coils [218], self-expanding platinum-coated Nitinol device [219], Chinese self-expandable occluder, similar to the Amplatzer occluder [220], Amplatzer Vascular Plug II [221], Cardio-O-Fix occluder [222], Nit-Occlud PDA-R (reverse) device [223] and perhaps, others.

Following the description by Cambier et al. [198] of the use of Gianturco coil [224] to occlude PDAs, a number of modifications of the coil and refinements of the technique have taken place and include snare assisted coil implantation [225], detachable coils [200-202], antegrade coil placement [226], multiple coil delivery [226], biotome-assisted coil deployment [277], temporary balloon occlusion of the ductus on the aortic [228] or pulmonary artery [229] side during coil implantation, five loop coil use [230], increasing the wire diameter to 0.052-in [231], coil delivery via a tapered tip catheters [232,233] and coil implantation without use of heparin [234]. Subsequent to the description of Amplatzer duct occluder [207,208], several modifications of the device to include, Amplatzer Angulated Nitinol plug [235,236], Amplatzer Swivel disk and plug occluder [237] and Amplatzer duct occluder II [238] were undertaken.

Although many devices are investigated, a few devices are approved by FDA for clinical use: Gianturco Coils, free and detachable, GGVOD and Amplatzer duct occluder. Several other devices are in clinical trials either in the US or in other countries. The interested reader referred elsewhere [189-191] for a more detailed discussion of historical aspects of PDA closure devices.

### Ventricular septal defect

Transcatheter closure of ventricular septal defects (VSDs) in dogs was initially described by Rashkind [130]; he used hooked single-disc device to accomplish this. Subsequently Lock et al. [239] used Rashkind's double disc PDA umbrella [136] in human subjects; the device was implanted successfully in six of the seven patients and the seventh embolized into the pulmonary artery. Goldstein and his associates [240] utilized clamshell occluder to close the VSDs. Perioperative closure of muscular VSDs was used in complex congenital heart defects as a part of overall management of the patients [241]. Subsequently, buttoned device [242,243], Amplatzer muscular VSD device [244,245], detachable steel coil [246], Gianturco coils [247], Amplatzer membranous VSD occluder [248], wireless devices (Detachable balloon & transcatheter patch) [249], CardioSEAL/STARFlex devices [250], Nit-Occlud (Nickel-Titanium Spiral Coil) [251], Amplatzer Duct Occluder [252] and Amplatzer Duct Occluder II [253] devices were used for transcatheter occlusion of VSDs.

Percutaneous closure of post myocardial infarction VSDs with Rashkind's double disc PDA umbrella [239], clamshell [254], CardioSEAL or STARFlex [254], Amplatzer septal occluder [255], Amplatzer post-infarct muscular VSD (PIMVSD) [256] and Amplatzer duct occluder [257] devices has also been attempted.

At the present time, Amplatzer muscular VSD and PIMVSD occluders, and CardioSEAL® Septal Occlusion System with QwikLoad and STARFlex Septal Occlusion System are approved by the FDA. Although the Amplatzer membranous VSD occluder was found useful, development of heart block [258] precipitated its removal from clinical trials in the US. Other devices are in clinical trials either in the US or

abroad and can only be used at institutions participating in clinical trials and will not be reviewed.

### **Aortopulmonary window**

Stamato and associates [259] appear to be the first to report transcatheter occlusion of aortopulmonary window (APW) using a Rashkind double umbrella PDA device and concluded that percutaneous closure is feasible in small APWs. Subsequently other workers used buttoned [260], Amplatzer duct occluder [261], Amplatzer septal occluder [262], Amplatzer muscular VSD occluder [263], Amplatzer perimembranous VSD occluder [263] and Shenzhen Lifetech Scientific Inc's muscular VSD occluder [264] devices to successfully close APWs. All authors [259-264] and others [265] that used percutaneous closure of APWs emphasize that APW is a rare congenital cardiac defect and that only a minority of APWs are of small size and are amenable to transcatheter closure.

### **Catheter-Based Atrial Septostomy**

#### **Rashkind balloon atrial septostomy**

Creation of atrial septal defects by transcatheter methodology was first described by Rashkind and Miller in 1966 [3] and was the only interventional therapeutic technique available for use in children until early 1980s. This technique, now called Rashkind balloon atrial septostomy, was extensively used to improve atrial mixing in neonates with transposition of the great arteries. Rashkind balloon atrial septostomy was subsequently extended to treat atrial level obstruction in patients with tricuspid atresia [266], pulmonary atresia with intact ventricular septum [267], total anomalous pulmonary venous connection [268] and hypoplastic left heart syndrome including mitral atresia [3,269].

When Rashkind first described balloon septostomy [3], he introduced the catheter into the femoral vein by cut-down. To avoid femoral venous cut-down, insertion of the catheter via the umbilical vein [270] and by percutaneous technique [271], when percutaneous technology became available, was adopted. While most cardiologists perform the procedure in the catheterization laboratory, the feasibility of performing balloon septostomy bedside, under echo guidance [272], has been demonstrated.

#### **Park's blade atrial septostomy**

In hypoplastic left heart syndrome patients as well in older patients, the lower margin of the PFO is thick and can't be ruptured by Rashkind balloon septostomy; such septostomy may simply stretch and not tear the lower margin of the PFO. Park and his associates [273,274] developed catheters with build-in blade (knife) to address such thick atrial septae; the lower margin of the PFO is cut with this catheter and is followed by conventional balloon septostomy.

#### **Balloon angioplasty of the atrial septum**

Balloon angioplasty or static dilatation of the atrial septum to keep an existing PFO open in animal models was experimented by Mitchell [275] and Sideris [276] and associates. Shrivastava et al. [277] reported the first clinical application of this technique in a neonate with transposition of great arteries.

#### **Trans-septal puncture**

In a small percentage of patients, the atrial septum is intact (no PFO). In such situations the septum can't be crossed with conventional

catheters. Traversing the intact atrial septum by Ross/Brockenbrough's trans-septal technique [278,279] is possible and has been extensively used in adult subjects [279]. Brockenbrough technique of trans-septal puncture was extended to pediatric patients [280] and more recently to neonates [281]. Alternatively, radiofrequency perforation [282] may be used. In either technique, once the left atrium is entered, static dilatation of the atrial septum (as described in the preceding section), cutting balloon septoplasty [283] or stent implantation (to be described in the next section) have to be performed to keep the atrial septum open.

#### **Atrial septal stents**

Because of tendency for closure of dilated atrial septal openings, stents to keep the defects open may have to be used. We proposed the concept of using stents for this purpose while discussing state of the art and future directions in interventional pediatric cardiology in 1998 [284]. The very following year Atz et al. [281] reported stent placement across the atrial septum after trans-atrial needle puncture in a neonate with hypoplastic left heart syndrome and intact atrial septum. Subsequently other reports of atrial septal stents appeared in the literature.

### **Other Transcatheter Interventions**

There are several other transcatheter interventions such as blunt guide wire or radiofrequency perforation of atretic pulmonary valve, transcatheter occlusion of unwanted superfluous vascular lesions such as cerebrovascular and hepatic arterio-venous fistulae, multiple aorta-pulmonary collateral vessels associated with pulmonary atresia with ventricular septal defect (tetralogy Fallot), anomalous systemic artery associated with pulmonary sequestration/scimitar syndrome and veno-venous or arterio-venous collateral vessels associated with bidirectional or Fontan procedures, transcatheter valve replacements and others that are not reviewed here because limitations of space.

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