

Cardiac Intervention in Congenital Heart Disease: a New Way to Look At the Old Problems

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Siriraj Med J 2008;60:152-158

E-journal: <http://www.sirirajmedj.com>

Interventional cardiology in congenital heart disease can be dated back to as early as 1966 by William Rashkind¹ for performing balloon atrial septostomy in patients with complete transposition of the great arteries (D-TGA). The early phase of cardiac intervention appeared to be palliative or complementary to surgical correction. The curative intervention for a specific congenital heart lesion was seldom performed. The true success to address a worldwide management for a simple congenital heart defect was the introduction of a widely used Amplatzer™ Septal Occluder for closure of large atrial septal defect (ASD) in 1997.² This was followed by a first case report in Thailand in 1999.³ Since then the development came at a rapid pace, such as a device for patent ductus arteriosus (PDA) or perimembranous ventricular septal defect (VSD) and transcatheter placement of the bioprosthetic valves in the pulmonary and aortic positions. 'Hybrid' techniques and collaboration with cardiothoracic surgeons, adult cardiac interventionists, and perinatologists are exciting new developments with far reaching implications.

This review will include the overview of historical perspective of cardiac catheterization intervention in congenital heart disease at Siriraj hospital. It will concentrate on four important topics including the transcatheter closure of secundum atrial septal defects (ASD), the patent ductus arteriosus (PDA), the perimembranous and subpulmonary (infundibular) VSD, the placement of a large peripheral stent in the pulmonary artery and coarctation of the aorta.

Historical perspective

The early case of balloon atrial septostomy was performed at Siriraj Hospital in late 1990s. The result was palliative in a patient who underwent an arterial switch operation which initially was performed exclusively in a cardiac catheterization laboratory. A subsequent echocardiographic guided procedure was also

performed at the bed side. After the initial balloon septostomy we have reported using a balloon catheter to perform a dilation of the pulmonary valve in patients with valvular pulmonary stenosis.^{4,5} At the early stage the balloon is somewhat bulky and cannot be safely used in a small infant or neonate. To allow a compromise solution for vascular access in newborns, we used a smaller size coronary balloon and instrument such as laser wire for patients with pulmonary atresia and intact septum.⁵ The procedure consisted of using laser energy to perforate the atretic pulmonary valve and then a coronary balloon angioplasty system to progressively dilate the pulmonary valve. The development of the Giaturoco coil also allowed us to use single or multiple coils for embolization of abnormal vascular structures such as an arteriovenous venous fistula or a small PDA in 1996.⁶ The introduction of a nitinol mesh wire self centering device allowed large defects for ASD or PDA to be successfully and safely closed. In the current year the interventional procedure consisted of 55-60% of all cardiac catheterizations that were performed at Siriraj Hospital for congenital heart patients both in children and adults.⁸⁻¹² The techniques for radiofrequency catheter ablation for treatment of supraventricular tachycardia patients¹³ and cardiac pacing¹⁴ have also been reported in children in our institute. The complexity of congenital heart disease such as in post-operative Fontan patients has allowed an opportunity to use a combination of procedures such as balloon angioplasty and stenting for pulmonary artery stenosis with coil embolization for arterial collaterals and device closure for a fenestrated Fontan in the same patient instead of multiple surgeries.¹⁵ The latest development of cardiac intervention has included the transcatheter closure of ventricular septal defect¹⁶ and primary stenting for large arteries such as the pulmonary artery or coarctation of the aorta.¹⁷ Table 1 shows the chronological sequence for cardiac intervention for congenital heart disease and the current situation of patients in 2008.

TABLE 1. Year of first intervention cardiac catheterization reported at Siriraj Hospital for congenital heart disease and current status and cases in 2008. AV = atrioventricular, ASD = atrial septal defect, SVT = supraventricular tachycardia, PDA = patent ductus arteriosus, MRI= magnetic resonance imaging, VSD= ventricular septal defect, ICE = Intracardiac echocardiography, Nit occluder = Nitinol coil for VSD closure.

Year	Lesion	Device	No. patients (publications)	No. patients 1995-2008	Comments
1996	AV fistula ⁶	Gianturco [®] coil	1	4	Large fistula using Vascular Plug [®]
1997	Pulmonary valve stenosis ⁴	Balloon catheter coronary or peripheral	27	237	
1998	Pulmonary atresia/ intact ventricular septum ⁵	Laser wire, Coronary balloon	1	6	Using radiofrequency ablation energy is also reported
1999-2000	ASD ⁸⁻¹²	Amplatzer [™] septal occluder	31	512	90% success up to 40 mm in diameter
2000	SVT ¹³	Catheter ablation of preexcitation pathway	21		
2002	PDA ²¹	Coil & Amplatzer [™] Duct occluder	77	256	For large PDA using either ASD or VSD device
2002,2004	ASD ⁸⁻¹²	Comparison with surgery and MRI	218		ICE for deficiency of inferior rim ASD
2003	Fontan ¹⁵	Stent/balloon/coil/ device occlusion	1	5	
2003	VSD ¹⁶	Amplatzer [™] perimembranous VSD	4	64	Nit Occluder for Subarterial VSD in 10 patients
2005	Coarctation of aorta/pulmonary artery ¹⁷	Palmaz Genesis [®] , CP stent	5	47	
2005	AV-block ¹⁴	Pacemaker	31		

Transcatheter device closure of secundum atrial septal defect

Secundum atrial septal defect (ASD) accounts for 10% of congenital heart disease at birth and as much as 30-40% of adults who present with congenital heart problems.¹⁸ It is generally agreed that an ASD associated with a large left-to-right shunt and either symptoms or significant cardiomegaly should be electively closed. Long-term follow up after atrial septal defect closure was reported by Murphy et al.¹⁹ It appeared that the long term survival of patients who had a surgical closure after the age of 25 was lower than that in patients who had surgery at a younger age. Closure of ASD at a later age may not prevent late morbidity, which includes persistent pulmonary hypertension, atrial tachyarrhythmia or paradoxical emboli. Surgical repair of an ASD is a safe and widely accepted procedure with negligible mortality. However, it is associated with morbidity, discomfort and a thoracotomy scar. As an alternative to surgery, a variety of devices for transcatheter closure of ASD have been developed.^{2,20} We initially reported our experience of transcatheter closure of atrial septal defect using the Amplatzer[™] Septal Occluder in both children and adults with intermediate term follow-up.^{3,8,9} A detailed description of the transcatheter closure technique has been given previously.^{3,8} In summary, the patients were intubated and placed under general anesthesia. A complete hemodynamic evaluation was performed. An angiographic picture was taken in the right pulmonary vein to delineate the anatomy of the ASD. An exchange 260 cm, 1 cm soft

superstiff guide wire was placed into the end hole catheter in the left upper pulmonary vein to exchange with a balloon occlusion catheter. This balloon catheter was inflated and pulled across the ASD to determine the stretched diameter. The Amplatzer[™] Septal Occluder² (AGA Medical Corp., Golden Valley, MN, U.S.A.) is constructed from 0.004-0.005 inches Nitinol (nickel and titanium) wires, tightly woven into two flat buttons (discs) with 4-mm connection waists. The device diameter (size) ranged from 4 to 38 mm with a customized 40 mm was later available. The prosthesis is filled with Dacron fabric to facilitate thrombosis. The device is attached by a micro screw mechanism to a 0.038 inches stainless steel delivery cable. It is loaded into a long sheath varying in size from 6 to 14 French. A device was selected to be the same size or 1 mm smaller than the stretched diameter. A long (7 to 14 F) guiding sheath and dilator were advanced over the guide wire into the left atrium. The loader with the collapsed device was then advanced into the sheath by pushing the delivery cable. Under fluoro-scopic and Transesophageal echocardiogram (TEE) guidance, the left atrial disc was deployed and pulled gently against the atrial septum which were both felt and observed by TEE. Then the waist and right atrial disc were deployed, respectively (Fig 1).

Since then over 500 patients who had secundum ASD successfully closed in our institute. We reported the results of a comparison of closure of ASD surgically with transcatheter closure using the Amplatzer[™] Septal Occluder which was comparable with other

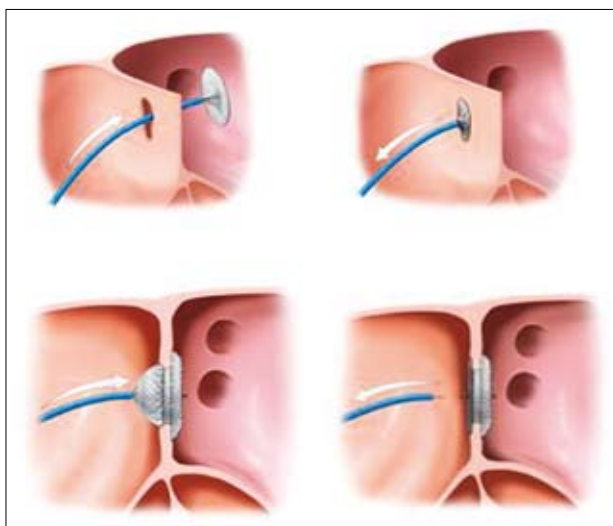


Fig 1. Stepwise deployment of Amplatzer™ septal occluder from (left atrial disc opening in the left atrium (left upper) then right atrial disc (right upper) and then both discs were opposed each other straddle the inter-atrial septum (left lower). Device was released by unscrewing the delivery cable (right lower).

studies in the western hemisphere^{10,21} as shown in Table 2. The technique for screening for a suitable candidate for closure such as cardiac magnetic resonance imaging¹¹⁻¹² or Intracardiac echocardiography (ICE) allowed us to better prescreen a patient with a large defect (> 40 mm) or a deficiency of posterior or posterior-inferior rim, multiple defect, or inferior defect. We also improved the deployment instrument and technique such as using a precurved braided sheath, simultaneous balloon occlusion, left upper or right upper pulmonary vein deployment. The average device size is 28-30 mm with more than 35% using a large device (> 30 mm) and more than 10 patients using the 40 mm device. The overall success rate for closure of ASD for all comers is 90%. Average fluoroscopy time was 21.5±7.9 min (11 to 38 min). The average procedure time was 81.87±22.3 min (40 to 120 min).

The major complication is embolization of the device in 9 patients (1.7%) which all occurred during the procedure. Three patients had a successful retrieval procedure of the device and redeployment of a larger

TABLE 2. Comparison between patients who had surgery (Group I) and device closure (Group II) adapted from early study.¹⁰

	Group I (n = 64)	Group II (n = 29)	p-value
Mean age at procedure (yr)	27.2±15.0	19.8±18.7	0.035
Weight (kg)	43.5±14.1	32.5±17.1	0.001
ASD size (mm)	28.4±10.2*	23.4±5.7**	0.003
Qp : Qs ratio	3.2±1.0	3.4±1.7	0.713
RVSP (mmHg)	51.4±17.1	40.2±11.9	0.005
Hospital day	7.9±4.4	1.2±1.3	< 0.001
Procedure time (min)	-	81.8±22.3	-
Fluoroscopic time (min)	-	21.5±7.9	-

ASD, atrial septal defect; Qp:Qs, ratio of pulmonary to systemic blood flow; RVSP, right ventricular systolic pressure; mm. Millimeter; min, minute.

*surgical measurement, **stretched diameter

device size. The other 6 patients underwent surgical closure. During the surgery all of them demonstrated a thin posteroinferior rim (< 5 mm). One 12 kg Down's syndrome patient also had a complete atrioventricular block immediately after the device was released and required a permanent pacemaker insertion. Retrospectively, this patient had a 20 mm ASD stretched diameter with a deficient aortic rim so a 26 mm device was chosen. Minor complication for the transcatheter closure of the ASD included transient arrhythmia in 1-2%, arterio-venous fistula at the puncture site in 2 patients which required surgical correction. Sporadic case reports of late erosions, usually of the anterior superior aspect of the atrial septum with perforation into the adjacent ascending aorta, are being reported with the Amplatzer™ device. This prompted AGA Medical to convene a panel of experts to analyze the available data in patients with this adverse event and compare them to the patients in the U.S. Multicenter Pivotal Study.²² Overall, 28 cases of late perforations have been reported to AGA (14 in the USA). The panel identified that adverse event patients were more likely to have a deficient anterior superior rim. They also determined that the device to unstretched defect diameter was larger in the adverse event group compared with the Pivotal Study group. The panel recommended that balloon sizing should be conservative using the flow occlusion method, and oversizing the device for patients with a deficient anterior– superior rim should be avoided. Furthermore, if a patient has a small pericardial effusion at 24 hours, closer follow up should be undertaken. We have implemented a strict policy by using a device to ASD diameter size (by TEE) to be less than 1.5:1. We did not encounter any case of cardiac perforation. Other indications for using this device including patients with a stroke or transient ischemic attack (TIA) resulting from a presumed paradoxical embolism through a patent foramen ovale (PFO) with 15 patients closed in this way. For a long term data, the device continues to perform well with excellent closure rates and minimal complications. Thrombus formation is a rare problem that can usually be treated medically and its incidence appears to be device dependent.²³

Transcatheter closure of PDA

Closure for a small PDA can be performed via a transcatheter using a regular 038 Gianturco Coil. However, it was limited to a PDA with diameter less than 3-4 mm.⁷ The significant number of patients with coil occlusion still had a residual shunt (Table 3). The development of the Amplatzer™ Duct Occluder allowed us to close a PDA as large as 12 mm.²⁴ For a PDA with severe pulmonary hypertension we prefer to use

TABLE 3. Comparison of patent ductus arteriosus (PDA) closure using either Amplatzer™ duct occluder (device group) for large PDA or Gianturco coil for small PDA with surgery.

	Device (80)	Surgery (56)	Coil (100)
Age (mo)	17.8±18.2	7.3±7.8	7.7±6.7
Weight (kg)	38.0±21.7	18.9±11	21.1±11.7
Diameter (mm)	5.9±2.7	7.2±4.2	2.5±0.9
Procedure time (min)	74.9±26.9	96.5±32.6	91.3±45.9
Residual shunt	1/80	4/56	25/100
Reoperation/cath	3	2/56	10/100
Hospital (days)	1.1±0.2	7.8±5.6	1.3±2.9

double discs device such as the Amplatzer™ muscular VSD device. Our study reported the comparison of closure of patent ductus arteriosus (PDA) surgically with transcatheter methods. Between 1999 and 2004, there were 226 patients who had PDA with the results of closure shown in Table 3. Overall surgical closure appeared to have a selected advantage for preterm infants or small children (weight less than 6 kg). However, surgery had a residual shunt with at least 3% of reoperation. The coil occlusion had its limitation due to only a small size of PDA could be successfully closed. It also had a higher chance of embolization with a high rate of residual shunt. The Amplatzer™ Duct Occluder is a new device for closure of large sizes of PDA with a success rate as high as 99%. The benefit for each patient was demonstrated in lesser morbidity, no surgical scar and a shorter time spent in the hospital.

Transcatheter closure of ventricular septal defects

Ventricular septal defect (VSD) is the most ubiquitous of all congenital heart disease (CHD). The reported incidence of isolated VSD ranges from approximately 0.4-4.6 per 1,000 live births.¹⁸ The total proportion of VSD in CHD was 16-50%. There are currently three types of VSD that potentially could be closed using transcatheter therapy: Perimembranous VSD (Pm VSD), muscular VSD and subpulmonary (infundibular out flow) VSD. Closure the defect was required if indicated by the patient's condition such as pulmonary overcirculation, symptomatic congestive heart failure, recurrent pneumonia, failure to grow, any complication of the defect; infective endocarditis, or if a prolapsed coronary cusp caused aortic regurgitation (AR). Percutaneous transcatheter closure VSD was initially attempted by Lock and associates.²⁵ Success was limited by the difficult implantation techniques, residual shunt, and device embolization and interference with the aortic valve. Recently, the development of the self-centering Amplatzer™ perimembranous VSD occluder (Fig 2) with a specially designed asymmetrical disc to avoid catching the aortic valve and prevent further aortic regurgitation.

For a selected subpulmonary VSD or perimembranous VSD with an aneurysm the Pfm Coil (Nit Occluder: Fig 3) is a new device²⁶⁻²⁷ that can be used for proper closure with a minimal interference with the aortic valve and also less chance of complete atrioventricular block (CAVB). From 2003 to 2008, 67 cases (53 perimembranous, 8 subpulmonary and 2 muscular) have been enrolled. There are 64 successful closures with 54

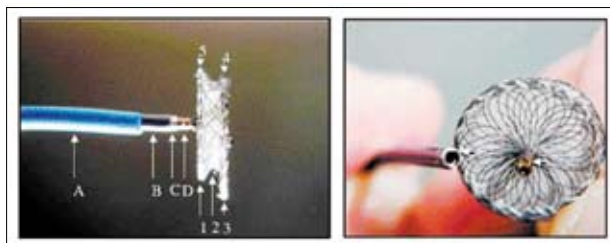


Fig 2. Amplatzer™ perimembranous (eccentric) ventricular septal defect (VSD) device on the side view (left) and enface view from right ventricular disc (right). The device showed a more caudally displaced left ventricular disc to avoid catching at aortic rim. A= delivery cable, B = pusher catheter, C= delivery cable, D = screw attachment to the device, 1= right ventricular disc, 2 = waist of the device and 3 = left ventricular disc.

using the Amplatzer Perimembranous VSD and 10 patients using the Pfm coil. Complete closure was obtained in 62 patients (96.8%). There were 4 patients who had complete AVB and 3 required a pacemaker placement. All of them had eventually normal sinus rhythm within 4 - 6 months. There were 2 residual shunts in the Pfm coil group.

Endovascular stent in congenital heart disease:

Traditionally pulmonary artery stenosis or coarctation of the aorta were treated using balloon angioplasty. However, some patients did not respond optimally to balloon angioplasty alone because of enhanced vessel elasticity, compliant obstruction, non-dilatable fibrotic lesion, kinking or external compression.. Mullins et al. first studied the use of balloon-expandable intravascular stents in pulmonary arteries and systemic veins in 1988.²⁸ Subsequently, O' Laughlin et al²⁹ described their stent applications in patients in 1991. Since then, stenting has gradually replaced surgical interventions and overcome conventional balloon angioplasty. However, the use of stents for treating the vascular stenosis in children is challenging, as ideally the final vessel diameter after stenting should ultimately approach the adult vessel size. Moreover, with a relatively small patient it makes these procedures sensitive for complications even in experienced hands.

From January 1999 to December 2006, 84 patients underwent therapeutic catheterizations at Siriraj Hospital for the treatment of significant vascular obstructive lesions such as stenosis in branches of the pulmonary

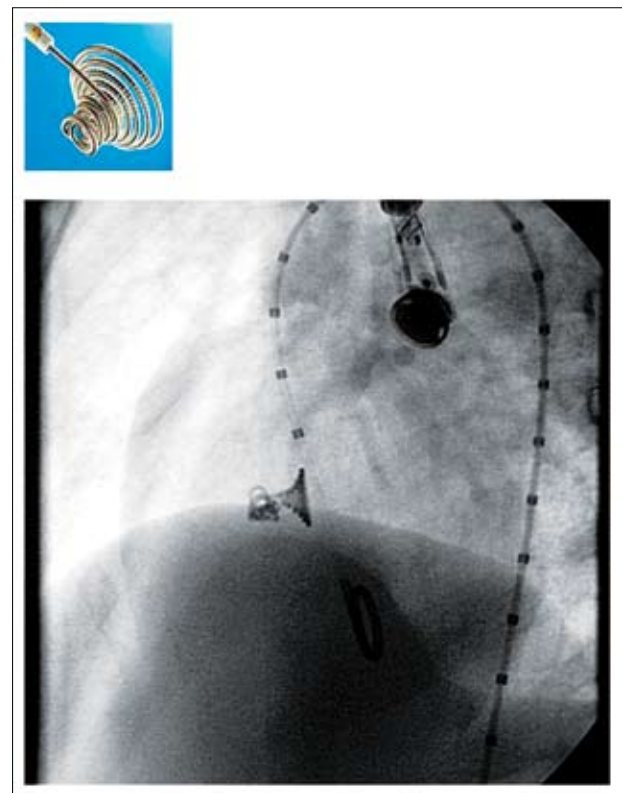


Fig 3. Nit Occluder which was made from Nitinol material demonstrated a stiffer coil property with conical shape as also shown here from the left ventricle fluoroscopic picture in the left anterior oblique (LAO) view of left ventricle. The device was shown facing into left ventricle (to the right of the picture).

artery, coarctation of the aorta, stenosis in the right ventricle (RV) to the pulmonary artery (PA) conduit, and stenosis in the systemic vein either congenital or post operative form. Thirty one patients underwent stent implantation and 53 patients underwent balloon angioplasty.

The previously used non-premounted stent was the large PALMAZ[®] stent (P308 from Johnson & Johnson Interventional Systems Co., Warren, NJ, USA). These stents have a recommended expanded diameter between 8-12 mm but are commonly over dilated to 18-20 mm with some difficulty. Later the PALMAZ[®] GENESIS[™] XD stent (Cordis /Johnson and Johnson) was introduced and replaced the PALMAZ[®] stent. It was designed to have lower profile, minimize shortening, add radial strength, and increase flexibility and can be expanded up to 18 mm while maintaining flexibility and excellent radial force. However, both stents still had significant foreshortening when the dilated diameter was approaching 15-16 mm. The smaller premounted stents are also available such as Express[™] Biliary SD and Express[™] Vascular LD (Boston Scientific Co., Natick, MA, USA). The recommended expanded-diameter of Express[™] Biliary SD is 6-8 mm while that of Express[™] Vascular LD is 9-11 mm. Both of the stents had a limit indication only to a small vessel. Currently, we have been using a platinum-based Cheatum (CP) stent which has a stronger radial force and less foreshortening after dilatation up to the diameter of 20 mm.

Techniques for implantation in each lesion were described in detail in previous reports.^{17,28-29} Briefly, the procedures were performed under general anesthesia and patients were fully heparinized with heparin 50-100 U/kg to maintain activated clotting time more than 250 seconds. Complete hemodynamic and angiographic assessments were performed. The largest stent that could be delivered safely was chosen to allow the possibility for future dilation. If it is not a premounted stent, the stent was mounted on 8-16 mm diameter low profile balloons and directed to straddle the lesions with a 10 or 11 Fr long sheath guide over a 0.035-in superstiff exchange wire (Meditech, Boston U.S.A.). After initial placement, the stent was subsequently inflated with a larger balloon to ensure stability and to eliminate any residual stenosis. Prophylaxis antibiotic was administered intravenously in every patient. A low dose of aspirin, 3-5 mg/kg/day, was routinely given after the procedure for 6 months.

84 patients were classified into balloon angioplasty (BA) or stent implantation (SI) group.

Balloon angioplasty group

This group consisted of 53 patients, 24 males and 29 females. The mean age at BA was 12.4 ± 10.7 years, ranging from 2 months to 42 years. The mean weight was 29.7 ± 17.4 kg (from 6.3 kg to 68.0 kg). The majority of cases were PA stenosis and coarctation of the aorta (CoA), 38/53 (72%) and 11/53 (21%) patients respectively.

Stent implantation group

In total, 33 stents were implanted in 31 patients, 14 males and 17 females. The mean age at SI was 14.3 ± 9.9 years, ranging from 23 months to 43 years. The mean weight was $34.8 \text{ kg} \pm 21.8$ (from 8.1 kg to 91.3 kg). The same as the BA group, the majority of cases were PA stenosis and CoA, 17/31 (55%) and 9/31

(29%) patients respectively. There were eleven cases (36%) that had undergone BA previously and had not responded optimally to BA.

Comparison between BA and SI groups has shown no statistically significant difference of age and body weight at intervention and fluoroscopic time. Angiographic and hemodynamic data before and after each procedure showed that SI had more significant anatomic and hemodynamic successes than BA, especially in post-dilation diameter ($p < 0.05$) and post-dilation systolic peak gradient (SPG: $p = 0.001$). Moreover, the percentage of diameter increments in the SI group was considerably higher yield than in the BA group, $125 \pm 90.7\%$ and $45.9 \pm 54.9\%$ respectively ($p = 0.02$). There was no statistically significant difference between the two groups in terms of post-dilation right ventricular systolic pressure (RVSP) and right ventricle (RV)/systemic pressure (Table 4).

Comparison of the anatomical and hemodynamic success between BA and SI has shown that the SI group had a higher rate of both anatomical and hemodynamic success (Table 5). Using anatomical success criteria, the SI group had 84% of patients reached success criteria while BA had only 27% of patients ($p < 0.001$). Not only anatomical success, but the SI group also had a higher rate of hemodynamic success. The SI group had 86% of patients whose post dilation SPG across the stenotic site was less than 10 mmHg while BA had only 61% of patients ($p = 0.03$). Besides almost ninety percent of SI patients had a SPG reduction of more than 50% whereas BA patients had a smaller percentage ($p < 0.01$). However, by using a post dilatation RV/systemic pressure reduction of more than 20%, there was no statistical significance between both procedures.

There was no major complication report and a low rate of morbidity in both procedures. Three patients in the SI group had complications. One patient with a single ventricle physiology developed a transient complete heart block during the procedure which lasted 24 hours. Massive bleeding from the right femoral vein developed in one patient while removing a broken long sheath, which was accidentally damaged during stent expansion. However, no surgical intervention was required in this case. There was only one patient in the BA group who had transient loss of femoral pulse after dilation of coarctation of the aorta which was completely recovered after 24 hours of intravenous heparinization. There was no aneurysm formation, pulmonary hemorrhage, pulmonary edema, or emergency operation in both groups. Our result has shown an early success rate of almost 90% with a better immediate outcome compared to a conventional balloon angioplasty due to a significant increment of vessel patency and decrement of pressure. In addition, in our series, late stent failure has been found in only 10% of patients and excellent long-term patency has also been shown in most cases. Moreover, it is a safe procedure with acceptable morbidity.

Future treatment of cardiac intervention in congenital heart disease

The expansion of available techniques for transcatheter devices, stents, and bioprosthetic valves have also their difficulties. In particular catheter-sheath manipulation within the heart and the large sheaths that

TABLE 4. Comparison demographic and acute results between balloon angioplasty and stent implantation (RVSP = right ventricular systolic pressure; mmHg, RV/LV% = right ventricle pressure to left ventricle pressure percentage).

	Balloon angioplasty (n=53)	Stent (n=31)	P
Age (yr)	12.4 ± 10.7	14.3 ± 9.9	NS
Body weight (kg)	29.7 ± 17.4	34.8 ± 21.8	NS
Fluoroscopic time (min)	34.5 ± 35.9	22.6 ± 10.7	NS
Stenotic diameter (mm)			
Pre-dilatation	7.0 ± 4.2	5.4 ± 2.2	0.02
Post-dilatation	9.1 ± 4.9	10.9 ± 2.9	< 0.05
% diameter increment	45.9 ± 54.9%	125 ± 90.7%	0.02
Pressure gradient (mmHg)			
Pre-dilatation	26.0 ± 17.3	27.7 ± 26.2	NS
Post-dilatation	14.0 ± 15.7	4.3 ± 5.7	0.001
% gradient reduction	18.6 ± 14.6	26.6 ± 20.0	NS
RVSP (mmHg)			
Pre-dilatation	58.6 ± 20.1	56.5 ± 31.4	NS
Post-dilatation	48.3 ± 19.5	52.0 ± 19.6	NS
% pressure reduction	22.0 ± 24.6	33.0 ± 53.1	NS
RV/LV pressure (%)			
Pre-dilatation	55.5 ± 19.1	59.0 ± 34.8	NS
Post-dilatation	41.7 ± 14.0	44.0 ± 11.1	NS
% pressure reduction	20.0 ± 19.0	24 ± 23	NS

are sometimes required, negate its use in the pediatric population. This has led many groups to develop a hybrid approach to the management of some simple as well as complex congenital cardiac defects.³⁰ Several groups have embraced this and now plan corrective repair prospectively with combined surgical and interventional techniques in mind. Close collaboration is required so that a surgical approach is modified to facilitate a subsequent interventional approach. The classical example is the management of a hypoplastic left heart syndrome (HLHS). Stage 1 palliation involves transcatheter creation of atrial septal communication and ductal stenting to maintain ductal patency with surgically applied external right and left pulmonary artery bands or transcatheter placed internal bands.³¹ Stage 2, a modified Norwood procedure with a bidirectional Glenn anastomosis, is predominantly a surgical approach with certain surgical modifications reported by Galantowicz and Cheatham (32) to facilitate stage 3 (Fontan operation) to be performed completely by transcatheter techniques.

Transcatheter valve replacement

Transcatheter placement of bioprosthetic valves in the pulmonary and aortic positions is now a recognized

procedure. (Sentence was incomplete – no verb or object, so I made up some words to complete it.) Dr. Philipp Bonhoeffer³² has used a bovine jugular venous valve mounted on a balloon-expandable Cheatham platinum stent for transcatheter delivery of a pulmonary valve in a RV to PA conduit for patients with conduit stenosis. The management for severe pulmonary regurgitation in a native outflow with transcatheter valve placement will certainly be coming in the near future.

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TABLE 5. Comparison of the anatomical and hemodynamic success between balloon angioplasty and stent implantation (RV = right ventricle).

	Balloon angioplasty		stent		p
	n/N	%	n/N	%	
Anatomical success	13/48	27	26/31	84	< 0.001
Diameter increased > 50%					
Hemodynamic success	23/38	60.5	24/28	85.7	0.03
Peak gradient < 10 mmHg	21/37	56.8	21/24	87.5	0.01
Decreased in peak gradient > 50%	14/24	58.3	5/10	50.0	NS
Decreased RV/systemic pressure > 20%					
Anatomical + hemodynamic success	8/25	24	25/30	83	< 0.001

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