Therapeutic Cardiac Catheterization for treatment of Congenital heart defects has become a routine mode of therapy in the present era. Catheter techniques have evolved to simplify future surgery, provide temporary palliation or offer even definite repair. These procedures are categorized as established, investigational or experimental.1 With improving hardware and increasing experience and expertise, more and more procedures are being performed with great degree of safety and efficacy. The major advantage of non surgical procedures is avoidance of scar, thoracotomy and cardiopulmonary bypass along with a shortened period of hospitalization and lesser post-operative pain and recuperation period.

Although transcatheter interventional procedures have a relative low risk, there are potential complications and therefore these procedures should not be used without an opportunity for benefit. These should necessarily be performed in catheterization laboratories fully equipped with the various catheters, guide wires, balloons and devices. They should be performed by a trained pediatric interventional cardiologist. The American Heart Association has laid down guidelines and recommendations on indications for pediatric therapeutic catheterization in various congenital heart diseases.2 These will need to be modified based on our own data from surgical and interventional procedures with respect to immediate and long term results.

Pediatric interventions can be broadly classified into:

- Transcatheter closure of congenital cardiac defects
- Balloon dilatation of stenotic vessels and valves (Balloon Angioplasty and Valvuloplasty)
- Atrial septostomy procedures
- Others.

Given the relatively recent nature of these procedures, randomized control studies of their safety and efficacy are still lacking. The results and complications of various procedures mentioned in this review are taken from the prospective and retrospective observational studies and registry data reported in the literature as well as from our own experience.3
A. Transcatheter Closure of Congenital Cardiac Defects

1. Closure of Atrial Septal Defect (ASD)

Device closure for ASD has been evolving since 1974, when Mills and King reported their experience with the non-surgical technique. Last decade has seen a plethora of devices being used for ASD closure. The important amongst them being Das Angel Wing, ASDOS, Button, Cardio Seal, Starex, Amplatzer septal occluder (ASO) and the Helex device. Some of them have been withdrawn due to inadequate safety, sub-optimum efficacy or lack of being user friendly; while the others are undergoing design modifications before being relaunched.

There is adequate data to indicate that transcatheter closure of secundum ASD is a viable alternative to surgery in selected patients. In a large multicentric study using Clampshell occlusion device, successful implantation was reported in 97% of the cases with 64% having complete closure and 35% having a small residual leak.\(^4\)\(^5\) The prerequisites for ASD closure include (1) The presence of a symptomatic or a large defect with pulmonary to systemic blood flow ratio of 1.5 or more (2) Weight greater than 8-10 kg (3) Central location of the defect with an adequate rim on all sides to support the prosthesis (4) Defect size of 30 mm or less. (5) The ability to tolerate short term antiplatelet therapy (6) The availability of an appropriate device.

Currently, the most common device used for ASD closure is the Amplatzer septal occluder (ASO). It can be used effectively in defects as large as 40 mm (stretched diameter). With over tens of thousands of implants used worldwide, its short term and intermediate term safety has been well established. Some of the advantages of this device are the user friendly design, a smaller delivery system, control over the device and the ease of retrieving and repositioning the device (without damaging it) before release. Bulkiness of the device and the possibility of predisposition to thrombo-embolism may be some of the drawbacks of the device but no clinically significant problems have been reported so far. Since October 1998, we have performed 236 cases using ASO at 17 different centers. ASD diameter of less than 30 mm with superior, inferior and posterior margins of greater than 5 mm and separation of greater than 7 mm from anterior mitral leaflet were the criteria for inclusion (Fig 1). The size of the ASD varied between 9 mm to 31 mm (mean 17.6 ± 5.1) with the device size varying between 11 to 40 mm. 9 patients were found to be unsuitable on table since the device size equaling the stretched diameter of the defect was not available.

![Fig. 1: Showing ASD closure by Amplatzer device](image_url)
patients, we failed to position the device in the appropriate position and hence the device was removed and the patients were sent for surgery electively. Over a follow up period of 1.5 to 56 months (26 + 8.6), 1 patient had a mild mitral regurgitation and 1 developed a small residual shunt through a tiny satellite defect. There were no other adverse events including device migration, thromboembolism or occurrence of arrhythmias. Very large ASDs (ASD requiring devices > 30 mm) has also been found to be amenable to effective transcatheter closure in an analysis of 31 patients with device requirement ranging from 30- 40 mm. Technical and clinical success was seen in most patients. Complete absence of anterior rim with a tiny superior rim appears to be an incremental risk factor for technical failure in this subset of patients. Similar encouraging results in larger number of patients have been reported, both from India and abroad. Major constraint to the use of such devices is their cost which currently is astronomical and makes this procedure more expensive than surgery in most of the centres in India.

2. Transcatheter Closure of Patent Ductus Arteriosus (PDA)

Transcatheter closure of patent ductus arteriosus has been established as a safe and effective option to surgical ligation. Transcatheter closure of a small PDA (<2.5mm) is done by using Gianturco coils which bring about closure of the PDA due to their thrombogenic potential. The immediate angiographic success rates have been reported to be about 60-65% with a single coil and 90% with the use of multiple coils. Our early experience using temporary balloon occlusion technique for coil closure of PDA showed an immediate complete closure in 60% of cases which increased to 95 % at end of 24 months as determined on Color Doppler. Only 3 out of 84 patients needed a repeat procedure for a significant residual shunt (Fig 2). With modifications in techniques (use of modified vertebral catheter, use of bioptome for coil delivery, use of multiple coils and proper patient selection i.e PDAs less than 4 mm), results have shown significant improvement in immediate angiographic closure which is now in the range of 90%. Other techniques such as coil delivery using a snare or use of commercially available controlled coil designs (PDA coils by Cook Inc, Duct occluder) have been described to increase safety and improve efficacy. Rashkind’s double umbrella device, Sideris ’s Button device and Amplatzer PDA device are some of the devices used for the closure of PDA; the former being withdrawn from the market due to high incidence of arm fractures. Since October

![Fig. 2: Showing PDA closure by coil.](Image)
1998, we have successfully deployed 174 Amplatzer PDA devices\textsuperscript{11} (Fig 3). All patients beyond the neonatal period with no branch PA stenosis or aortic isthmic narrowing were considered suitable for the procedure (the youngest being 3 month old and weighing 3.2 kg). The minimum PDA diameter on angiogram varied between 2-11 mm (mean 3.44 ± 1.22), with a mean procedural time of 56.25 min and uoroscopy time of 6.18 min. There were no major or minor complications during the procedure. All, except one had complete closure of PDA, at the end of two weeks. At 6 weeks to 56 months of follow up, none had residual shunt across the PDA.\textsuperscript{12} Two patients weighing less than 5 kg and requiring devices of greater than 6/4 size developed significant gradients across LPA (velocity of greater than 2.5 m/sec).

Neonatal PDA, especially in a premature infant, does not have a well developed ductal diverticulum on the aortic side. Moreover, many of these children have a high pulmonary artery pressure. None of the currently available devices nor the coils can get anchored in these ducti. Thus surgical ligation remains the procedure of choice in this subgroup. Residual shunts, coil / device embolization, left pulmonary artery stenosis, aortic isthmus narrowing and hemolysis are some of the complications reported with transcatheter closures. With increasing experience and expertise, the complication rate has come down remarkably.

3. Transcatheter Closure of Ventricular Septal Defect (VSD)
Transcatheter closure of muscular VSDs using Amplatzer VSD occluder has been reported by Thanopoulos et al with encouraging short and intermediate term results.\textsuperscript{13} Studies by the same author on the transcatheter closure of perimembranous VSD with the Amplatzer septal defect occluder have also shown promising preliminary results.\textsuperscript{14}

4. Transcatheter closure of Unwanted Vessels or AV fistulas
Aortopulmonary collaterals arise from the thoracic aorta or its branches in patients with cyanotic congenital heart disease and contribute to improved oxygen saturation. However, they can have adverse effects before, during and after surgical repair. They are known to obscure the operative field, reduce perfusion pressure on cardio pulmonary bypass, distend the left ventricle and compete with effective sources of pulmonary blood ow in the pulmonary vasculature. Therefore all significant collaterals need to be closed.
preferably before surgery. What constitutes a “significant” collateral vessel is a matter of controversy but any collateral that has an angiographically documented pulmonary venous return should be closed. A large collateral which would reduce the saturation to below 70% or a collateral which is the only source of pulmonary blood ow or the ones which can be easily accessed before establishing a CPB could be left alone at the time of cardiac catheterization. Although transcatheter closure of unwanted vessels can be accomplished by the use of vascular “glues” and detachable balloons, Gianturco coils remain the most preferred technique (Fig 4). These coils are versatile and exible and can be delivered through catheters as small as 3F. Moreover they can be reliably retrieved following inadvertent embolisation. Since the coils close the collateral vessels due to clot formation, some groups soak the coils in thrombin solution to promote thrombosis. The most common complication of coil closure of aortic collateral is embolism to the lungs. Most of these coils can be retrieved with the use of snares. Other minor complications include fever, pleural rub and occurrence of small pleural effusion.

Surgically created aortopulmonary shunts can lengthen or complicate intracardiac repair and can be closed in the catheterization laboratory. However, the decision to close them preoperatively or intraoperatively must be made jointly by the cardiologist and the cardiac surgeon.

Transcatheter techniques have also been used for the closure of pulmonary and coronary AV fistulas. Although Gianturco coils are most commonly used, detachable balloons, Grifka bag,Amplatzer PDA /ASD device have also been successfully used for transcatheter closure of these fistulae. In our experience since 1995, of transcatheter closure of 11 patients (between the ages 1.17 to 9 years) with coronary cameral fistulas, we found the procedure safe and effective both in short and immediate term follow up. Single or multiple Gianturco coils were used in 7 with 2 patients requiring detachable balloons and coils and one patient requiring Gianturco and electrolysis-released platinum coils. It is important to realise that different strategies consisting of route of delivering the closure material and different types of anchoring devices need to be evolved depending on the anatomy of the fistula, size of the patient and availability of the hardware. Collaboration between interventional cardiologist and radiologist may be beneficial.
B. Balloon Dilatation of Vessels and Valves

Vascular or valvular stenoses are dilated by deformation or rupture through circumferential stress using a balloon. Dilating balloons are usually made of transparent polyethylene with a diameter ranging from 2.5 – 30 mm and with lengths of 2-10 cms.

1. Transcatheter dilatation of valves:

Stenotic valves can be opened by the use of balloon catheters which results in splitting of the commissures and dilatation of the annulus. The balloon is rapidly inflated to a recommended pressure till the waist in the balloon disappears. Pressure gradients are recorded before and after the dilatation to assess the success of the procedure. Balloon valvuloplasty can performed for (a) Dilatation of stenosed pulmonary valve (BPV) (b) Dilatation of stenosed aortic valve (BAV) (c) Dilatation of membranous subaortic stenosis (d) Dilatation of mitral and tricuspid valve and (e) Dilatation of bioprosthetic valves.

   a. Balloon pulmonary valvuloplasty (BPV): BPV is the treatment of choice for children with pulmonary valvular stenosis (PS). It is effective and safe and provides relief of obstruction equivalent to that obtained following surgery. The only exceptions being those with dysplastic valves and neonates with critical PS where the results are less gratifying. Balloon valvotomy is recommended for transvalvular gradients above 50 mm Hg or if RV pressure is greater than 50% of systemic pressure (Fig. 5).

BPV can also be used as a palliation to reduce severe cyanosis in selected patients with congenital heart lesions. The procedure is shown to have a significant improvement in the growth of pulmonary annulus and the pulmonary artery branches. We have limited experience of palliating children having TOF with BPV with a success rate of 80% lasting for a period of 6 months. In neonates and children with pulmonary valve atresia and intact IVS, it is possible to perforate the pulmonary valve with the hardware of the GW or RF wire. Many groups have reported successful perforation of pulmonary valve using these techniques.

   b. Balloon aortic valvuloplasty (BAV): In comparison to pulmonary balloon valvuloplasty, aortic dilation is technically demanding and carries higher morbidity
and mortality. This is particularly seen in infants with poor left ventricular function or those with hypoplasia of left sided structures. At present BAV is indicated in children with peak systolic gradients greater than 60 mm Hg without significant aortic regurgitation and in infants with critical obstruction and left ventricular dysfunction regardless of the gradient. The reported complications include transient left bundle branch block, aortic valve incompetence, complete atrio-ventricular block and transient loss of femoral arterial pulsations. In over 175 reported cases, the mean gradient reduced from 68-108mm to 24-41mm Hg post procedure (Fig. 6) At follow-up, there was no re-stenosis or change in regurgitation. Significant hemodynamic and clinical improvements were observed in 60-80% of the neonates with critical aortic stenosis. Trans-carotid approach for neonates and trans-septal antegrade approach have also been described for balloon aortic valvuloplasty. In our own experience, sick neonates with LV dysfunction are at highest risk for procedure related complications.

c. Dilatation of stenosed Mitral valve: Significant mitral stenosis can lead to pulmonary edema, alveolar fibrosis, pulmonary artery hypertension and right ventricular failure. Balloon valvuloplasty has supplanted closed surgical valvulotomy for symptomatic, non-calcified rheumatic mitral stenosis. Although it can be used in children with congenital mitral stenosis, the results are much less gratifying in terms of efficacy with high incidence of complications. Usually patients with cuspal tear, papillary muscle avulsion and with pre-existing severe pulmonary hypertension tolerate MR poorly and need early surgical intervention. Immediate success rates range from 64-100% depending on the anatomy of the valve. Results of gradient reduction persist for a long time in valves with good morphology.

2. Vascular Balloon Dilatation
Successful vascular balloon dilatation involves controlled longitudinal or oblique, intimal and sometimes medial tear. Current indications for vessel dilatation are: narrowing of pulmonary artery branches, native CoA and stenosis of individual pulmonary veins and major systemic veins.

1. Dilatation of Coarctation of Aorta: There is a general agreement that percutaneous
angioplasty represents the procedure of choice for recoarctation of aorta following surgery. However, there is no unanimity of opinion regarding the role of balloon angioplasty for native coarctation. This is primarily due to early reports of aneurysm formation in as high as 6-45% of cases within 1-3 years after dilatation. However, with the present day practice of using smaller balloons at lower pressures the incidence of such aneurysms has lowered. The major limitation of balloon coarctoplasty in neonates and small infants (less than 3 months) is the high rate of restenosis. The overall rate of complications in 230 reported procedures was about 6% (Fig 7). The advantages are high primary success rate, low complication rate and shorter duration of hospital stay in critically ill patients with high operative risks.

In children with tubular hypoplasia of the aortic isthmus, the use of intravascular stents has greatly reduced the incidence of restenosis. Endovascular stents are extremely useful in preventing restenosis. In our experience of primary stenting in 15 patients above 10 years of age with coarctation of aorta, there was a marked decrease in the stenotic gradient from 59.13 + 8.8 mm Hg pre-procedure to 5.26+ 12.93 mmHg post procedure. No major complications were seen except in one patient who had delayed left femoral artery thrombosis requiring embolectomy. On a follow up period of 3-49 months there was no evidence of re-stenosis.

2. Dilatation of Pulmonary artery stenosis: Pulmonary artery stenosis occurs as discrete isolated branch stenosis, multiple distal stenoses or as a tubular hypoplasia. These are amenable to balloon angioplasty and endovascular stents with an overall complication rate of 10% and mortality rate of 1-2%. Most often these stenosis occur as a part of a congenital heart disease such as TOF with pulmonary atresia. When it occurs in isolation or with other intracardiac defects it could be a part of Rubella syndrome, William’s or Allagille’s syndrome.

3. Dilatation of Pulmonary veins & systemic veins: Therapeutic balloon dilatation of individual pulmonary veins is still investigational and considered as the last resort due to lack of a realistic surgical alternative. However, the overall long term results of balloon dilatation of pulmonary veins with or without stents appear dismal. Major systemic veins (SVC & IVC) are more amenable to stent dilatation with gratifying results.

Fig 7: Balloon dilatation of coarctation of aorta.
C. Atrial Septostomy Procedures
Balloon atrial septostomy (BAS) is indicated as a palliative procedure for congenital heart lesions in neonates and young infants in order to improve mixing as in d-TGA or to enlarge the obligatory, restrictive, inter-atrial communication as in the case of mitral or tricuspid atresia. In infants older than 1 month, a blade followed by balloon septostomy is recommended to achieve satisfactory results. The overall complication rate is 8-10%. In our own experience of 73 cases who underwent echo guided BAS for various indications, there was no mortality and there were no major complications.

D. Other Intervention Procedures
Catheter therapy is also used for:
1. Non-surgical foreign body removal – like catheter fragments, therapeutic occlusion devices, and embolised foreign bodies. Commonly used retrieval devices are baskets, bioptomes and snares.
2. Transcatheter myocardial biopsy is helpful for etiological diagnosis of various myocarditis, cardiomyopathies and for the diagnosis of rejection in patients with cardiac transplantation.
3. The transcatheter radiofrequency ablation of accessory pathways has revolutionized the treatment of several forms of childhood arrhythmias.
4. Laser balloon angioplasty has been reported in experimental animals to preserve the patency of ductus for palliative shunting.
5. Collaborative therapeutic catheterization and surgical procedures have been attempted, e.g. Transcatheter completion of Fontan’s after a surgical bidirectional Glenn and peroperative transventricular closure of VSD using a device on a beating heart.

Summary
Pediatric cardiac interventional program is not a one-man effort. It requires a well knit team consisting of pediatric cardiologist, an intensivist, an anaesthesiologist, nurses and trained cardiac catheterization laboratory personnel. It is necessary to have a surgical back up in case of complications warranting surgical intervention.

In order to know whether or not these procedures are as effective and as safe as their currently available surgical counterparts, it is essential to have a regular and complete follow up of these children. This is an area where physicians and pediatricians can actively contribute by timely referral. Main issues that need to be addressed during the follow up are short term success, long term success and procedure related complications.

The major constraint for these procedures is their cost. However, it is expected that the prices will come down in the next few years with increasing competition and indigenous production of some of these materials.

In conclusion, pediatric cardiac interventions are here to stay given their track record of safety and efficacy. However, it is important to realize their scope and limitations so that a right procedure is offered to the right patient. With the current rate of growth in technology, they are bound to replace more and more surgical procedures in the years to come.

References