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Pediatric Therapeutic Cardiac Catheterization A Statement for Healthcare Professionals From the Council on Cardiovascular Disease in the Young, American Heart Association

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Introduction

During the last few years, dramatic changes have taken place in the pediatric cardiac catheterization laboratory.¹⁻⁴² Improved noninvasive diagnostic techniques have narrowed the indications for diagnostic cardiac catheterization, and the laboratory is now increasingly being used for therapeutic procedures. Concern about the appropriateness of some applications of pediatric therapeutic cardiac catheterization has arisen recently because of numerous catheter techniques, the increased numbers of persons and centers using these techniques, and the increased number of lesion types thought to be amenable to catheter therapy.

In comparison with diagnostic cardiac catheterization, therapeutic catheter procedures require more time and resources, are costlier and riskier, and demand more technical training and expertise. High levels of skill are required of the operator who performs the various therapeutic catheterization techniques. These procedures should only be performed in institutions with appropriate facilities, personnel, and programs.⁴³ These considerations, combined with the rapid increase in the number of laboratories and cardiologists performing therapeutic catheterization procedures, cause concern about hospital and physician credentialing, hospital and physician peer review, and human subjects investigational review. Since publication of the last American Heart Association statement on pediatric therapeutic cardiac catheterization,⁴⁴ many new devices and applications have been described, prompting this report on important new techniques in pediatric therapeutic cardiac catheterization. Because much of the information in this statement is still investigational, this statement does not formally represent American College of Cardiology/American Heart Association (ACC/AHA) guidelines. However, the authors believe that the recommendations, which are classified as I, II, and III, represent a consensus. Interventional electrophysiological procedures are not addressed.

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Personnel Requirements

Therapeutic catheterization training programs vary in type, extent, and quality. Because of the complexity and potential risks of these procedures, specific credentialing criteria should be developed for those who wish to begin performing therapeutic catheterization as well as for those who continue to perform various procedures.

Performance of therapeutic catheterization in children requires specific training. Pediatric cardiology fellows should receive therapeutic catheterization training in one or more centers that carry out angioplasties, valvuloplasties, and/or vascular occlusion procedures. Before performing a therapeutic catheterization as the primary operator, the fellow or practicing pediatric cardiologist should be required to receive procedure-specific training under the supervision of a qualified individual similar to that required of internist cardiologists who wish to perform coronary angioplasties.⁴⁵ Credentialing should be procedure specific. To maintain his or her credentials, the cardiologist should perform or supervise an adequate number of cases annually to maintain skills, and the results must compare favorably with national experience. The cardiologist must be aware of new trends and information through reading and attendance of meetings. However, attending "how-to" seminars and observing experts does not obviate the need for personal experience. An ACC/AHA task force report states that "it is essential that physicians performing angioplasty and related procedures are adequately trained, that facilities and equipment used are capable of obtaining the necessary radiographic information, and that the safety record of the laboratory is acceptable."⁴⁶ The emphasis of this report is on formal credentialing and documentation of training, competence, and ongoing maintenance of skills.

The facility, hospital, quality assurance programs, and laboratory personnel associated with the pediatric therapeutic catheterization program must meet applicable national standards of the ACC/AHA Ad Hoc Task Force on Cardiac Catheterization.⁴³

Facilities and Equipment

A catheterization laboratory in which therapeutic catheterization procedures are performed should be used regularly for all types of congenital cardiac catheterization procedures. The radiographic equipment must be of the highest quality and capable of producing high-resolution images. The equipment must be constantly serviced and regularly replaced or upgraded to maintain the high quality of imaging. Tube angulation systems are necessary. Biplane fluoroscopy/cineangiography

must be available in any laboratory in which therapeutic pediatric and congenital cardiac catheterizations are performed. A large and complete inventory of specific equipment is needed. A variety and complete stock of emergency devices such as retrieval catheters are also required.

The institution in which the catheterization laboratory exists must be committed to therapeutic procedures and support of laboratory requirements. The institution must also have a cardiovascular surgical service for immediate treatment of emergencies that may occur during therapeutic catheterization procedures. To maintain proficiency in techniques and to justify the cost of equipment, personnel should regularly and frequently perform specialized therapeutic procedures. A sterile operating room environment must be maintained for many procedures. The sites of implanted devices are exceptionally susceptible to infection.

Opening of Atrial Communications

Balloon Atrial Septostomy

Balloon atrial septostomy was first described by Rashkind and Miller² in 1966 as a palliative procedure for transposition of the great arteries. Creating an atrial septal defect (ASD) in patients with transposition of the great arteries enhances bidirectional mixing of the pulmonary and systemic venous blood, improving oxygen saturation. The efficacy and safety of this procedure have been demonstrated.⁴⁷⁻⁵² Over the years there have been improvements in catheter design that may lower the complications of failure of deflation or balloon rupture,^{50,51,53,54} but the basic concept has remained. Balloon atrial septostomy can be done from both the umbilical vein or the femoral vein. Traditionally the procedure is done in the catheterization laboratory under fluoroscopic guidance. In lifesaving situations the procedure can be done in the intensive care unit under echocardiographic guidance.^{52,55-66}

Although balloon atrial septostomy is usually a safe procedure, complications have been reported. Transient rhythm disturbances are frequent⁶⁷; on rare occasions they can be permanent or fatal. Premature ectopic beats are the most common, followed by supraventricular tachycardia, atrial flutter, and fibrillation. Partial or complete heart block and ventricular arrhythmias also may occur. Failure to create an adequate communication is a possibility if the balloon is not withdrawn across the atrial septum rapidly enough or if the balloon is not an adequate size. This possibility increases with the infant's age (older than 2 months) because the septum is thicker. Other potential complications include perforation of the heart^{49,67-70}; balloon fragment embolization⁷¹; laceration of the atrioventricular valves⁴⁹; systemic, or pulmonary veins; and failure of balloon deflation.⁷²⁻⁷⁶ In the series reported by Venables,⁴⁹ four procedures failed and one patient died. Parsons et al⁶⁷ reported 6% failures of procedures.

Indications for Balloon Atrial Septostomy

- I. Conditions for which there is general agreement that balloon atrial septostomy is appropriate: Infants less than 6 weeks old with
 - a. Transposition of the great arteries, with or without associated cardiac defects. However, if the infant is

hemodynamically stable with adequate oxygenation and surgery is to be performed within 12 to 24 hours, there may be no added benefit from balloon atrial septostomy.

- b. Total anomalous pulmonary venous connection with restrictive ASD (before surgery if necessary)
 - c. Tricuspid atresia with restrictive ASD
 - d. Mitral valve atresia if the Norwood approach is not contemplated
 - e. Pulmonary atresia/intact ventricular septum
- II. Conditions for which balloon atrial septostomy may be indicated:
 - Hypoplastic left heart syndrome to partially, but not totally, relieve the gradient across the atrial septum
- III. Conditions for which there is general agreement that balloon atrial septostomy is inappropriate:
 - a. Interrupted inferior vena cava
 - b. Infants older than 1 to 2 months. The atrial septum is usually thick and not amenable to balloon septostomy.

Blade Atrial Septostomy

When the atrial septum is too thick to be torn adequately by balloon septostomy alone (in infants older than 6 weeks), and when the presence of an adequate atrial communication is essential for enhanced mixing, blade atrial septostomy is the preferred procedure. This procedure, first described by Park et al,⁴ has proved safe and effective in two collaborative studies^{22,77} and many other reports, even in adult patients.⁷⁸⁻⁸²

The blades (Cook, Inc, Bloomington, Indiana) are available in three sizes: 9.4, 13.4, and 20 mm. The protocol and technique of blade atrial septostomy has been described in detail.⁸³ The procedure traditionally is performed under fluoroscopic guidance. However, it can be done with echocardiographic monitoring.⁸⁴

Although the procedure is considered safe, there are potential complications. Perforation of the right atrium and ventricle^{22,80,81} has been reported during prolonged manipulation of the blade. Other complications include air embolism and inability to retract the blade into the catheter.⁸¹

Indications for Blade Atrial Septostomy

Blade atrial septostomy is performed when an adequately sized atrial communication is needed to enhance mixing at the atrial level or to decompress a chamber.

- I. Conditions for which there is general agreement that blade atrial septostomy is appropriate: Infants older than 6 weeks with
 - a. Transposition of the great arteries, with or without associated cardiac defects. However, if the infant is hemodynamically stable with adequate oxygenation and the arterial switch is to be carried out within 12 to 24 hours, there may be no added benefit from blade atrial septostomy.
 - b. Total anomalous pulmonary venous connection with restrictive ASD (before surgery if necessary)
 - c. Tricuspid atresia with restrictive ASD
 - d. Mitral valve atresia if the Norwood approach is not contemplated
 - e. Pulmonary atresia/intact ventricular septum

- II. Conditions for which blade atrial septostomy may be indicated:
 - a. Hypoplastic left heart syndrome to partially, but not totally, relieve the gradient across the atrial septum
 - b. Patients with pulmonary vascular obstructive disease and increased right atrial pressure
 - c. Infants older than 1 to 2 months. The atrial septum is usually thick and may not be amenable to blade septostomy.
- III. Conditions for which there is general agreement that blade atrial septostomy is inappropriate:
 - Interrupted inferior vena cava

Static Balloon Atrial Dilation

As mentioned above, when the atrial septum is thick (more than 6 weeks after birth), blade atrial septostomy is the preferred method of enlarging the atrial communication. However, the blade septostomy must always be followed by a balloon septostomy, which still has limitations in a thick, tough septum. To overcome such limitations, static balloon atrial dilation was first introduced in laboratory animals in 1986 by Mitchell et al⁸⁵ and then in humans in 1987 by Shrivastava et al.⁸⁶ This technique was proved to be relatively safe and effective.^{23,87} The use of oversized balloons to create a large defect was described by Ballerini et al⁸⁸ with very good results. Numerous cases in which the static balloon dilation technique was used have been reported in the medical literature.²⁴

The indications for static balloon dilation of the atrial septum are similar to those of balloon/blade septostomy.⁸⁹ If the patient is older than 6 weeks and the atrial septum is very thick or tough, a static balloon dilation can be considered, preferably to supplement the blade incision.

Closure Devices

Devices for Atrial Septal Defects

ASD is a common form of congenital heart disease accounting for approximately 7% of all defects.⁹⁰ Secundum ASD is the most common and is amenable to transcatheter closure. The standard for managing clinically significant ASDs is surgical closure, which is associated with less than 1% mortality. The incidence of residual shunting on long-term follow-up is as high as 7.8%,⁹¹ and significant morbidity⁹² is associated with surgical closure.

The era of transcatheter closure of ASD began in 1976, when King et al⁹³ reported the first application of a double-umbrella device in humans.²⁰ However, because of the large delivery catheter (23F) needed to introduce the umbrella, this device was not adopted by many cardiologists. Rashkind developed a single, self-expandable umbrella with hooks to close ASDs. This device underwent limited clinical trials that were stopped because of the low success rate of implantation.⁹⁴ Current devices that have undergone or are undergoing clinical trials are reviewed below.

Clamshell™ Device★

In 1989 Lock et al²⁵ developed the Clamshell double-umbrella device for closure of experimental ASDs in lambs. Later the

Food and Drug Administration (FDA) approved a clinical Investigational Device Exemption (IDE) trial of the device in selected cardiac centers. The device underwent extensive clinical evaluation^{94,95} with a very high success rate of implantation. An ASD less than 13 mm was found to be the only echocardiographic predictor of effective closure using the Clamshell device.⁹⁶ The trial was suspended because of the high incidence of incidental device arm fracture (42%)⁹⁷ discovered on follow-up chest radiography and the high incidence of residual shunt (27% to 44%).^{97,98} The device underwent design modification (change of metal, arm angles, and enhancement of the joint in the middle of the arms) by a new manufacturer and is now called the Cardioseal™ Septal Occluder (Nitinol Medical Technologies, Inc, Boston, Massachusetts). At press time, this device has received FDA approval for a clinical IDE randomized trial; guidelines for closure with this device are not yet available.

Buttoned Device★

In 1990 Sideris et al⁹⁹ reported on the use of a new “buttoned” device (Custom Medical Devices, Amarillo, Texas) for transcatheter closure of ASD. This device has three components: occluder, counteroccluder, and loading wire. The first use of this device in humans was reported in 1990 in three patients.¹⁰⁰ Since then hundreds of patients worldwide have undergone closure of an atrial communication.^{101–104} On long-term follow-up, the incidence of residual shunting across the defect is 34%, 28%, and 20% at 6, 12, and 24 months, respectively.¹⁰⁴ The major limitation of the buttoned device is unbuttoning and device embolization.¹⁰⁵ The incidence of unbuttoning has decreased from 11.1% with the first-generation device to 3.1% with the third generation¹⁰³ and to 1.1% with the fourth generation. The device has not undergone a clinical IDE trial nor has it been approved by the FDA. Initial clinical experience with a new centering buttoned device has been encouraging.¹⁰⁶ Reddy et al¹⁰⁷ published objective echocardiographic criteria that can be used to achieve a higher likelihood of successful closure of an ASD with the buttoned device.

Angel Wings™ Device★

To overcome limitations of the Clamshell and buttoned devices, Das et al¹⁰⁸ developed the Angel Wings device (Microvena Corp, Vadnais, Minnesota), a self-centering double-disk device made of superelastic nitinol and dacronlike material. The device and protocol for its implantation have been described.¹⁰⁸ The initial results in a multicenter FDA pilot study of the Angel Wings device have been encouraging.²⁷ The device is awaiting evaluation under an FDA-approved IDE protocol.

Atrial Septal Defect Occluder System Device★

Another device awaiting FDA approval for a clinical IDE trial is the atrial septal defect occluder system (ASDOS) device (Osyepka Corporation, Rheinfelden, Germany). This double-umbrella device is made of nitinol and polyurethane. For deployment, simultaneous venous and arterial access is necessary. The device has been used clinically,^{109,110} and the results of the initial phase have been encouraging.¹¹¹

All of the ASD devices require transesophageal echocardiographic guidance for optimal placement.¹¹² Three-dimensional

*Please see “Acceptance and Approval Status of Therapeutic Catheterization Procedures: Implications for Usage.”

transesophageal echocardiography may help in preselection of patients for device closure.¹¹³ As a consequence, the use of general anesthesia may be beneficial.

Indications for Use of ASD Devices*†

- I. Conditions for which there is general agreement that ASD devices are appropriate:

Patients with secundum ASDs or patients with patent foramen ovale and an associated stroke (or a transient ischemic attack) who meet the following criteria:

 - a. ASD diameter less than 20 mm
 - b. The presence of sufficient rim of tissue (at least 5 mm) surrounding the defect
 - c. Patients with fenestrated Fontan lateral tunnels if temporary balloon occlusion is tolerated¹¹⁴
 - d. Patients with right-to-left atrial shunt and hypoxemia
- II. Conditions for which ASD devices may be indicated:

None
- III. Conditions for which there is general agreement that ASD devices are inappropriate:
 - a. Sinus venosus ASD
 - b. Primum ASD
 - c. Secundum ASD with significant other forms of congenital heart disease requiring surgical correction

Devices for Ventricular Septal Defects

Surgical closure of muscular ventricular septal defects (VSDs), particularly those associated with other complex cardiac lesions requiring repair, is associated with high surgical mortality and morbidity. Therefore, preoperative transcatheter closure using a double-disk device can be helpful.

The Clamshell device, the Rashkind double-umbrella port deviceTM, and buttoned devices have been used to close muscular and/or perimembranous VSDs with variable degrees of success.^{21,28,115–117} In small infants with muscular VSDs and other complex defects, intraoperative device closure may be beneficial.¹¹⁸

Currently none of the available devices are approved for clinical investigations for VSD closure. Therefore, no recommendation can be made as to criteria for selection of patients or devices. Consideration will always have to be given to proximity of the defect to the atrioventricular or semilunar valves.

Devices for Patent Ductus Arteriosus*

The era of transcatheter closure of PDA dates back to 1967, when Porstmann et al¹¹⁹ reported the use of an Ivalon plug to close PDAs. However, because of the large size of the introducer needed to insert the plug (16F), his technique was not widely adopted. In 1979 Rashkind et al¹⁸ reported on a small hooked umbrella occluder device for transcatheter closure of PDA. The double-umbrella, nonhooked Rashkind PDA occluder evolved from that early umbrella. The Rashkind device is available in two sizes, 12 mm and 17 mm, delivered through 8F and 11F sheaths, respectively.¹⁹ The Rashkind umbrella device underwent investigation in extensive regulated clinical trials and is approved for routine PDA

closure in all major countries except the United States and Japan. The incidence of residual shunting using this device varied between 38% at 1 year and 8% at 40 months using color flow mapping and Doppler echocardiography and 0% to 5% using clinical criteria.^{120,121}

Rao et al¹²² reported their experience using the Sideris buttoned device for transcatheter closure of PDA using a 7F sheath with a 14% incidence of residual shunting at a mean follow-up interval of 6 months by color flow mapping and 7% by clinical criteria. Verin et al¹²³ reported the use of the BotallocluderTM for transcatheter closure using sheath sizes varying between 10F and 16F, with an incidence of residual shunting of 3% at a mean interval of 3.2 years.

Indications for Rashkind, Buttoned, or BotallocluderTM Devices in Countries Other Than the United States*

- I. Conditions for which there is general agreement that PDA closure is appropriate:
 - a. Symptomatic patients with the diagnosis of PDA
 - b. Asymptomatic patients with continuous murmur
 - c. Asymptomatic patients with color Doppler evidence of PDA and a systolic heart murmur
- II. Conditions for which PDA closure may be indicated:

Silent ductus detected on echocardiography performed for other reasons
- III. Conditions for which there is general agreement that closure is not appropriate:

PDA with irreversible pulmonary vascular obstructive disease

Grifka et al²⁹ developed a new vascular occlusion device that has been approved by the FDA for use in humans. The Gianturco-Grifka Vascular Occlusion device (Cook Inc, Bloomington, Indiana) consists of a nylon sack attached to an end-hole catheter. A modified spring guidewire is advanced through the end-hole catheter and into the sack. The wire coils expand the sack, which occludes the vessel or patent ductus. The coil-filled sack is then released from the catheter. This use of this device has been evaluated in animals¹²⁴ and humans³⁰ with very good initial results.

Indications for the Gianturco-Grifka Vascular Occlusion Device

- I. Conditions for which there is general agreement that use of this device is appropriate:
 - a. Aortopulmonary collaterals: This device is effective for complete closure of collaterals; a device 1 mm larger than the vessel should be used.
 - b. Patent ductus arteriosus (PDA): patients with a PDA at least 1 1/2 times greater than the diameter of the device to be used, corresponding to the Toronto angiographic classification of PDA type A1 (possibly A2), C, D, E, but not B¹²⁵
- II. Conditions for which this device may be indicated:

None
- III. Conditions for which there is general agreement that this device is inappropriate:

None

*Please see "Acceptance and Approval Status of Therapeutic Catheterization Procedures: Implications for Usage."

†At press time, all uses of ASD devices are investigational.

Balloon Dilation of Cardiac Valves

Pulmonary Valve Stenosis

Since the initial description of balloon valvulotomy in 1979 by Semb and colleagues⁶ and dilation balloon valvuloplasty in 1982 by Kan and coworkers,⁷ there have been numerous reports regarding successful initial and medium-term results of balloon dilation of pulmonary valve stenosis.^{126–130} Percutaneous balloon dilation effectively reduces right ventricular systolic pressure and transpulmonary gradients in most patients. Complications are rare; pulmonary regurgitation may occur in some patients but is typically mild and inconsequential.¹³¹

Balloon dilation remains the treatment of choice for pulmonary valve stenosis. The indications for pulmonary valve balloon dilation should be essentially the same as those for surgical pulmonary valvotomy. Specifically those include a transpulmonary valve gradient greater than 50 mm Hg for a patient with normal cardiac output. In critical pulmonary valve stenosis, the pulmonary valve pressure gradient may be significantly higher or lower than 50 mm Hg, depending on cardiac output and right ventricular function. This is especially so in the newborn. Both experience and advances in equipment have made balloon dilation for critical pulmonary valve stenosis more feasible and safe in recent years, and now it compares favorably with surgical pulmonary valvotomy for that lesion.^{31,32,132}

In typical pulmonary valve stenosis in the older infant or child, patient selection often relies on Doppler echocardiographic-estimated gradients. Generally, because these compare closely to catheter-measured peak-to-peak gradients, it is appropriate to use a Doppler echocardiographic-estimated gradient cutoff of 50 mm Hg for scheduling catheterization. In the catheterization laboratory, with the patient sedated, less stringent gradient criteria may be appropriate because of the low morbidity and mortality of the dilation procedure.

The use of balloon valvuloplasty in the patient with a dysplastic pulmonary valve has been debated. Depending on the pulmonary valve annulus and the diameter of the supra-valve stenosis, smaller balloons may be required, and results may be suboptimal. However, it may be worthwhile to attempt balloon dilation of these dysplastic valves to avoid or delay surgery, and overall results have been generally reasonable.^{12,13} Some guidelines regarding which valves may be more or less favorable for balloon dilation in pulmonary valve dysplasia have been suggested by a number of authors.^{133–135}

Balloon pulmonary valve dilation has been used successfully in patients with tetralogy of Fallot and other forms of cyanotic heart disease in which valvular pulmonic stenosis is an important feature. Although there appears to be some additional risk involved with using these procedures due to the potential of initiating hypercyanotic episodes, the overall results are encouraging. The procedure may allow the main and branch pulmonary arteries to grow while lessening the chance for dangerous “spells.”^{136–138} Balloon dilation is not useful for treatment of infundibular pulmonary stenosis unassociated with pulmonary valve stenosis.

Aortic Valve Stenosis

Since the initial description of balloon dilation of the aortic valve in children by Lababidi et al,¹³⁹ several investigators have

followed with reports of good short- and medium-term results of balloon aortic valvuloplasty.^{33,34,140–149} The transaortic pressure gradient and left ventricular peak systolic pressure can usually be reduced with balloon valvuloplasty, and the improvement appears to persist in patients beyond infancy; the low mortality associated with balloon dilation is similar to that seen with operative valvotomy. As with surgery, causation or worsening of aortic regurgitation can result from balloon dilation; the prevalence and degree of aortic regurgitation appears to be comparable with either approach.³⁵ Iliofemoral arterial injury and occlusion can occur after balloon dilation, especially in infants; however, development of very-low-profile balloons that can be inserted through small arterial sheaths has lessened the chance of arterial injury and thrombosis. Although continued evaluation of the safety and long-term efficacy of balloon dilation in aortic valve stenosis is required, it now represents an accepted alternative to open-heart surgery and aortic valvotomy.^{150,151} As in pulmonary valve stenosis, the indications for performing this procedure are the same as for the patient in whom surgery would be considered. However, patients who have significant aortic valve regurgitation are not considered candidates for balloon valvuloplasty.

Fewer data about balloon dilation of subaortic stenosis are available.^{152,153} There have been a few successful cases of balloon dilation of discrete membranous subaortic stenosis, but long-term efficacy remains unknown, and this condition continues to be designated Class II. Fibromuscular or tunnel-like subaortic stenosis and supra-aortic stenoses are not amenable to balloon dilation, and these indications remain Class III.

Mitral Valve Stenosis

Investigators have reported successful reduction of transvalvular mitral gradients with balloon dilation.^{10,11,154–156} Most published experience has been in adults. Experience with rheumatic mitral valve stenosis has been more widespread and successful than that with congenital stenosis.^{157,158} A number of complications have occurred, including left ventricular perforation, complete atrioventricular block, mitral valve leaflet damage, and severe mitral valve regurgitation. Because the commonly used prograde approach requires passage of one or two catheters across the interatrial septum, small residual ASDs may result. The risk of ASD may be lessened with the use of a dual catheter technique,^{154–156} and residual ASDs of significance appear to be uncommon with use of the Inoue balloon dilation technique, which has enjoyed extremely favorable initial and medium-term results.^{36,159–161} Balloon dilation valvuloplasty is now an acceptable alternative to surgical treatment for rheumatic mitral valve stenosis. The efficacy of this technique for congenital mitral stenosis continues to be evaluated. In experienced hands, balloon dilation of congenital mitral valve stenosis may allow delayed surgery. This may be important for the patient for whom additional size is required before eventual mitral valve replacement. The procedure is very technically demanding and requires a high level of expertise and experience.

Stenosis of Prosthetic Conduits and Valves Within Conduits

Using balloon dilation techniques, several investigators^{162,163} have successfully reduced gradients across stenotic areas of

prosthetic conduits and valves within them. The success of this procedure depends on the etiology of the obstruction and appears to be most likely when there is discrete obstruction at a stenotic valve. Compression of the conduit between the sternum and the heart mass and intimal peel formation are less likely to respond favorably, as is obstruction at the ventricular egress of the conduit. Obstruction at insertion of the conduit into the pulmonary arteries may be more amenable to balloon relief. Complications of the procedure include dislodgment of an intimal rind, embolization of calcium from the valve itself, and balloon rupture with embolization of foreign material. The areas of narrowing within the conduit may expand with balloon dilation and then recollapse with deflation of the balloon; this type of obstruction may be more responsive to balloon dilation with stent placement (see "Stents").

Indications for Balloon Dilation of Cardiac Valves

- I. Conditions for which there is general agreement that balloon dilation is appropriate:
 - a. Pulmonary valve stenosis
 - b. Congenital (noncalcific) aortic valve stenosis
 - c. Rheumatic mitral valve stenosis
- II. Conditions for which balloon dilation may be indicated:
 - a. Dysplastic pulmonary valve stenosis
 - b. Congenital mitral stenosis
 - c. Stenosis of prosthetic conduits and valves within them
 - d. Pulmonary valvular stenosis in complex cyanotic congenital heart disease, including some cases of tetralogy of Fallot
 - e. Discrete membranous subaortic stenosis
- III. Conditions for which there is general agreement that balloon dilation is inappropriate:
 - a. Infundibular pulmonary stenosis unassociated with pulmonary valve stenosis
 - b. Fibromuscular subaortic stenosis
 - c. Hypertrophic cardiomyopathy with subaortic obstruction
 - d. Supravalvular aortic stenosis

Balloon Angioplasty

Balloon Dilation of Coarctation of the Aorta

Surgery has been the standard therapy for coarctation of the aorta, but the operation is associated with certain morbidity and mortality. The feasibility of coarctation angioplasty was first demonstrated by Sos et al¹⁶⁴ in 1979, who showed that excised segments of coarctation of the aorta could be dilated. The technique was used clinically by Lock and others.^{8,16,165-169}

Indications for balloon dilation of coarctation of the aorta are essentially the same as those for surgery: hypertension proximal to the coarctation with a resting systolic pressure gradient across the narrowed segment greater than 20 mm Hg or angiographically severe coarctation with extensive collaterals. The mechanism of relief of coarctation with balloon dilation involves tearing of the intima and often the media of the vessel. It has been thought that scar formation from a previous operation would help protect a dilated segment from rupture and/or aneurysm formation. There is controversy about balloon dilation of coarctation of the aorta related both to risk of aneurysm formation after angioplasty and whether

dilation should be performed only on recoarctation or on both recoarctation and native disease.¹⁷⁰

Native Coarctation

Data on balloon angioplasty of native coarctation continue to accumulate.^{8,167,170-177} Balloon dilation has been effective in patients from 3 days of age to adulthood. The pressure gradient across the coarctation site can be decreased significantly with an angiographically apparent increase in the diameter of the narrowing. The systolic pressure gradient has been reduced to less than 10 mm Hg in about 50% of patients and less than 20 mm Hg in 77% to 91% of patients.¹⁷⁸ Although a complication rate of 17% was reported in the summary data of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry,¹⁷³ most complications were related to arterial injury in the smaller patient. These have declined with the use of lower-profile sheaths and balloons. Aneurysms, both acute and late, have been reported in 2% to 6% of these children.^{173,178} A number of authors have noted a distinction in success rate between newborns (less than 30 days old) and older patients. Data from the series by Fletcher et al¹⁷⁸ and others¹⁷⁹ suggest that the need for reintervention within a very short period of time is as high as 60% to 70% in infants, whereas no additional intervention was required in 88% of patients older than 7 months. Patients with isthmus hypoplasia and other unfavorable anatomic constraints such as long segment narrowing respond less well to balloon angioplasty, whereas discrete membranous or hourglass-type constrictions appear to respond more favorably.

Because effective palliation with balloon angioplasty can be accomplished in the great majority of patients older than 7 months, and because the risk of aortic aneurysm formation appears to be relatively low, balloon dilation may be appropriate for initial treatment in anatomically favorable aortic coarctations in patients over that age.¹⁸⁰ Further evaluation of the safety and efficacy of balloon dilation of coarctation in younger patients is necessary before it can be recommended.

Recoarctation of the Aorta

A number of patients, especially those with repairs made when they were infants, who have had surgical repair of coarctation of the aorta develop persistent or recurrent obstruction (recoarctation) at the repair site.¹⁸¹⁻¹⁸⁸ Reoperation may carry a significant risk of morbidity and mortality.¹⁸⁹⁻¹⁹³ In a multicenter study of 200 patients with balloon dilation of recoarctation, an effective reduction in pressure gradient was seen.³⁷ The multicenter study demonstrated relief of recoarctation in approximately 78% of patients who underwent the procedure. Five patients died; two of the deaths (1%) were related to the procedure itself. Complications of the procedure noted in this initial multicenter study included femoral artery damage and occlusion in 8.5%; this rate is expected to diminish with low-profile catheters and sheaths. The incidence of neurological events, although low, should decrease even further with conscientious administration of heparin. When balloon rupture is not included as a complication and technical improvements are considered, the complication rate is expected to be less than 10%. Late aneurysm development has been rare.¹⁹⁴ On the basis of this and other studies, it appears that balloon

angioplasty is a preferable alternative to surgery for treatment of recoarctation of the aorta.

Branch Pulmonary Artery Stenosis

Branch pulmonary artery stenosis and hypoplasia may be associated with a variety of cardiac malformations and often represent postoperative narrowings. These stenoses often require relief because they may cause right ventricular pressure overload, exacerbate pulmonary regurgitation, and increase resistance to flow across the total pulmonary bed (which may be deleterious in Fontan-type operations). In some series the acute success rate for branch pulmonary artery dilation is as high as 60%, with success defined as an increase of at least 50% of the predilation diameter of the stenotic area or a 20% decrease in the systolic right ventricular to aortic pressure ratio.^{195,196} Complications have occurred, including arterial rupture, unilateral or segmental pulmonary edema, hemoptysis, and thrombosis. Risk of mortality has been related to pulmonary artery rupture.¹⁹⁷ However, the surgical approach to and relief of branch pulmonary artery stenosis is often unrewarding because of the location and course of the left pulmonary artery, which dives posteriorly away from the surgeon, and the right pulmonary artery, which courses behind the aorta and may be difficult to enlarge. In addition, these areas often have scarring and adhesions from previous surgeries. Because of these surgical obstacles, catheterization attempts at balloon angioplasty for branch pulmonary artery stenosis are justified.

Both the initial results of balloon dilation of branch pulmonary artery stenosis and long-term follow-up may be improved in some patients by implantation of endovascular stents. Studies concerning the use of stents in branch pulmonary arteries have been encouraging, and this form of treatment may be one of the primary choices in patients who are old enough and large enough to allow implantation of adequately sized stents (see "Stents").

Systemic Venous and Pulmonary Venous Stenosis

There have been numerous reports of successful balloon dilation of systemic venous stenoses, especially in patients who have postoperative narrowings due to repair of sinus venosus ASD or Mustard or Senning operation. In addition, superior vena caval stenosis may occur in patients with sclerosing mediastinitis due to malignancy or other causes. Balloon dilation (with or without stent implantation) has proved effective in a great majority of patients and is associated with little morbidity and mortality.¹⁹⁸ Surgery for these residual stenoses or other forms of superior vena caval stenosis is difficult and somewhat unrewarding. Balloon dilation of these lesions is recommended as a preferred alternative to surgery. Again, the addition of stents to the armamentarium may increase overall success in central vein stenoses.

In contrast to the success observed with systemic venous obstruction, the limited experience with pulmonary vein stenosis dilation has been almost uniformly futile. Even when some initial successes were reported, stenosis recurred in virtually every instance.

Systemic-to-Pulmonary Artery Shunts

Systemic-to-pulmonary artery shunts have been dilated successfully.¹⁹⁹⁻²⁰¹ The chance of success may be better in patients with classic Blalock-Taussig shunts than in those without tissue-to-tissue anastomoses. However, even modified Blalock-Taussig shunts with prosthetic material tubing or central shunts can be dilated if there is a discrete stenosis at the anastomotic site. As with many of the interventional procedures described in this statement, surgical backup support must be available when any type of shunt is dilated because of the danger of thrombosis or dislodgment of prosthetic intimal lining. However, with these caveats, dilation of systemic-to-pulmonary artery shunts appears reasonable and may be attempted before repetition of a surgical shunt procedure is considered. With the recent popularity of the bidirectional Glenn operation as a substitute for a second systemic-to-pulmonary artery shunt, this procedure may be required in fewer instances. PDA dilation has been described as a palliative measure in a few patients,²⁰² but there are not enough data to include that indication as a Class I procedure.

Indications for Balloon Angioplasty

- I. Conditions for which there is general agreement that balloon angioplasty is appropriate:
 - a. Recoarctation of the aorta
 - b. Systemic vein stenosis
 - c. Pulmonary artery stenosis
- II. Conditions for which balloon angioplasty may be indicated:
 - a. Systemic-to-pulmonary artery shunts
 - b. Native coarctation (with appropriate anatomy) in patients older than 7 months
 - c. PDA
- III. Conditions for which there is general agreement that balloon angioplasty is inappropriate:
 - Pulmonary vein stenosis (to date virtually uniformly unsuccessful)

Although there are no published data comparing cost-effectiveness of balloon dilation with surgery for the lesions discussed above, a 1-day hospital admission for cardiac catheterization and treatment of a valve or vessel stenosis should be less costly than surgery for the same problem. The effectiveness appears to be similar for many of the problems reviewed. The only lesion for which surgery would be deemed permanently effective therapy rather than one of a series of palliations is pulmonary valve stenosis; the same is true for balloon dilation. If other catheterization procedures delay surgery, even with a small chance of eliminating the need for it, they play a part in reducing the overall number of operations a patient needs over a lifetime. In some cases, such as treatment of recoarctation and branch pulmonary artery stenosis, balloon treatment appears to be superior to surgical treatment because of the technical difficulties of operation or reoperation.

Stents

In recent years balloon-expandable stents have assumed an increasingly important role in pediatric therapeutic catheterization procedures. Balloon-expandable stents implanted

with a balloon dilation catheter serve as endovascular prostheses that maintain the patency of stenotic vessels and vascular channels. Stents are particularly useful in dilatable lesions whose intrinsic elasticity results in vessel recoil after balloon dilation alone.

In pediatric applications, the Palmaz balloon-dilatable stent (Johnson & Johnson, Warren, New Jersey) is the most commonly used.²⁰³ It consists of a slotted stainless steel tube available in two diameters and varying lengths. The smaller stent (2.5-mm diameter) can be dilated to a maximum of 9 to 10 mm and is suitable for smaller vessels. The larger Palmaz stent (3.4-mm diameter) can be expanded to a maximum of 19 to 20 mm. The Palmaz stent is implanted percutaneously through a 7F to 8F sheath (smaller stent) or a 10F to 11F sheath (larger stent) and is dilated to the desired diameter with an appropriately sized balloon catheter. Experimental studies have shown that when the Palmaz stent is apposed to a vessel wall, its surface becomes endothelialized within 8 to 10 weeks of implantation; portions of the stent not apposed to vascular walls do not endothelialize and can be potential sites of thrombus formation.^{204–206}

The Palmaz stent has been approved by the FDA for use in adults with peripheral arterial disease (eg, iliac or renal artery stenosis) due to atherosclerotic disease. The stent has not been specifically approved by the FDA for pediatric use, although recent clinical trials have shown the stent to be of significant clinical value in children with a variety of obstructive lesions.

Pulmonary Artery Stenosis

The most common application of balloon-expandable stents in pediatric cardiology has been in children with pulmonary artery stenosis and/or hypoplasia.^{207–213} The Palmaz stent is particularly valuable in pulmonary artery stenosis, which is dilatable but recurs immediately on deflation of the dilation balloon because of vessel recoil. Stenting of pulmonary arteries may be a reasonable first-line therapy because, compared with balloon angioplasty alone, pulmonary artery stenting appears to have a higher immediate success rate and a lower medium-term incidence of restenosis.^{214,215}

A multi-institutional study reported the outcome of 121 Palmaz stent placements in 85 patients.²¹⁰ Eighty stents were implanted in the branch pulmonary arteries of 58 patients ranging in age from 1.2 to 36.2 years. The majority of these patients had undergone previous surgical repair of tetralogy of Fallot or pulmonary atresia with VSD. After stenting, mean pulmonary artery diameter increased by 146% from 4.6 mm to 11.3 mm. There was associated immediate hemodynamic improvement and a substantial increase in flow to the ipsilateral lung documented by nuclear perfusion studies. Follow-up cardiac catheterization was performed in 25 patients who had previously placed pulmonary artery stents 8.6 months after stent implantation. There was evidence of restenosis in only one patient: a ridge of tissue had developed between two right pulmonary artery stents that did not overlap. The stenosis was relieved by redilation. In a recent study pulmonary artery stenting was shown to have clear clinical benefits in terms of improved hemody-

namics and alleviation of symptoms. Planned pulmonary artery surgery was deferred or avoided.²¹¹

When pulmonary artery stents are implanted in growing children, the need for future stent enlargement should be anticipated. Stent redilation has been shown to be safe and effective in stents implanted in pulmonary arteries for up to 3 years.^{210,211,216} The safety and effectiveness of late redilation of aortic stents have not been demonstrated.

Systemic Venous Stenosis

Balloon-expandable stenting also provides effective therapy for many patients with systemic venous obstructive lesions. The most common situation in pediatric cardiology occurs in patients who have obstruction of the superior or inferior systemic venous limb of an atrial baffle after Mustard or Senning repair of transposition of the great arteries. In a small number of such patients it has been reported that stenting of the superior limb, or less commonly the inferior limb, of an atrial baffle produced near-complete resolution of hemodynamic and angiographic obstruction.^{217,218} Short-term (2 to 13 months) follow-up cardiac catheterizations in several patients documented a modest degree of neointimal hyperplasia resulting in a small decrease in lumen diameter, but there was no measurable increase in pressure gradient.²¹⁷

Balloon-expandable stents have also been used successfully to treat superior or inferior vena caval stenosis in children and adults.^{217,219–221} Stenting appears to provide excellent short- and intermediate-term relief of such large venous obstructions, which may be associated with the presence of indwelling central venous lines after cardiac catheterization or in patients who have mediastinal malignancy, either before or after radiation therapy.

Other Applications of Endovascular Stenting

Endovascular stent implantation has also been reported in small pediatric series for treatment of stenotic right ventricle-to-pulmonary artery conduits,^{208,210} stenotic aortopulmonary collateral arteries,^{208,222–224} coarctation of the aorta,^{225,226} to maintain ductus patency in infants with ductal-dependent pulmonary or systemic blood flow,^{227–229} and to treat pulmonary vein stenosis.^{207,209,230} The total experience with any of these stent applications is too limited to draw conclusions about their usefulness. However, stent treatment of pulmonary vein stenosis has been uniformly unsuccessful.

Indications for Stenting

- I. Conditions for which there is general agreement that stenting is appropriate:
 - a. Pulmonary artery stenosis
 - b. Superior or inferior vena caval stenosis
 - c. Systemic venous obstruction at the superior or inferior baffle limb after atrial repair of transposition
- II. Conditions for which stenting may be indicated:
 - a. Stenotic right ventricle-to-pulmonary artery conduit
 - b. Stenotic aortopulmonary collateral vessels
 - c. Coarctation of the aorta
 - d. PDA in infants with ductal-dependent pulmonary or systemic flow

- III. Conditions for which there is general agreement that stenting is inappropriate:
Pulmonary vein stenosis

Coil Occlusion

Percutaneous transcatheter occlusion of unwanted vascular communications has played an important role in pediatric interventional cardiology since first described by Gianturco and colleagues⁵ more than 20 years ago. The most commonly used coil embolization materials available include the Gianturco stainless steel coil (Occluding Spring Emboli; Cook, Bloomington, Indiana) and the platinum microcoil (Target Therapeutics, Santa Monica, California). The Gianturco coil is constructed of stainless steel wire of varying helical diameters and lengths to which Dacron fibers have been attached to increase thrombogenicity.²³¹ After implantation of the Gianturco coil, occlusion of the vascular communication occurs as the result of thrombus formation and subsequent organization.^{232,233} A detachable Gianturco coil-delivery system is also available (Cook) that can facilitate some occlusion procedures because the coil can be withdrawn if it is not in optimal position. Platinum microcoils can be delivered through 3F delivery catheters (eg, Tracker 18, Target Therapeutics) introduced coaxially through 5F catheters positioned subselectively to occlude very small vessels.

The technique of therapeutic coil embolization varies, depending on the type of vascular connection to be occluded and the specific pathophysiology. General technical comments can be made, however. Embolization is always performed through a vascular sheath to allow multiple catheter exchanges and coil withdrawal or retrieval if necessary. It is essential that selective angiography be performed before embolization to define the size and structure of the vascular connection to be occluded. Preferably angiography is performed with the same catheter in the same position used for coil delivery. In general, coil occlusion is performed with a coil with a helical diameter 20% to 30% larger than the diameter of the target vessel or malformation. Approximately 5 to 10 minutes after coil implantation, selective angiography is performed to document vessel occlusion. If necessary, additional coils may be implanted. Systemic heparinization has been shown not to adversely affect the coil occlusion process.²³³

Aortopulmonary Collaterals

Perhaps the most common use of coil embolization techniques in pediatric cardiology is transcatheter occlusion of aortopulmonary collateral vessels.^{38,39,234–237} Aortopulmonary collaterals occur most commonly in children with tetralogy of Fallot or pulmonary atresia with VSD and may require transcatheter embolization before and/or after surgical intervention. Aortopulmonary collaterals are also observed in children with a univentricular heart after a bidirectional Glenn or modified Fontan procedure and in children with D-transposition of the great vessels. Occlusion of aortopulmonary collateral vessels can be physiologically advantageous by diminishing competitive pulmonary blood flow, reducing systemic ventricular volume overload, and assisting in the complex process of pulmonary artery unifocalization. Aortopulmonary collateral vessels to be occluded

- must supply a segment of the pulmonary arterial tree that receives dual arterial supply (ie, from the central pulmonary artery as well as from the collateral) and
- must not be required for adequate systemic arterial oxygen content.

Patent Ductus Arteriosus

For decades cardiologists have sought an effective transcatheter method of closing the PDA. A variety of devices have been investigated, including Ivalon plugs and umbrella devices, but all require large delivery catheters and are expensive. Coil occlusion of the patent ductus is simple and effective. It requires only a 4F or 5F catheter and is relatively inexpensive. Since first described in 1992, coil occlusion of the restrictive PDA has rapidly become the treatment of choice at many institutions.^{40,41,238–243} It provides effective therapy for the large majority (more than 90%) of restrictive PDAs when the minimum angiographic diameter is less than 4 mm.²⁴³ Coil embolization has also been described for the larger but still restrictive PDA with a minimum diameter of 4 to 7 mm.²⁴¹ The coil occlusion technique is not appropriate for the nonrestrictive PDA, and its use in the clinically silent PDA has also been questioned.²⁴⁴

Coil occlusion of PDA can be performed transarterially or transvenously and may require implantation of one or more coils. The use of a snare catheter to hold the pulmonary artery end of the coil during transarterial delivery may facilitate successful PDA occlusion.²⁴⁰ Follow-up data have shown that tiny residual shunts noted immediately after coil implantation often resolve spontaneously.²⁴³ A recent retrospective study has found that hospital charges are substantially lower for coil occlusion than surgical ligation even when charges associated with surgery for residual PDA after coil occlusion are taken into account.²⁴⁵

Complications related to PDA coil occlusion include a persistent residual shunt in 5% to 10% of cases, embolization of a coil to the pulmonary artery or rarely to a systemic artery requiring catheter retrieval, occasional femoral artery injury following cannulation with a 4F to 5F catheter, and very rarely hemolysis associated with a residual shunt. Important left pulmonary artery stenosis, coarctation, clinical thromboembolism, endarteritis, or late recanalization have not been reported after PDA coil occlusion.

Surgical Aortopulmonary Shunts

In some children with a surgical aortopulmonary shunt (eg, Blalock-Taussig), residual shunting persists following a more definitive surgical procedure. Transcatheter coil embolization provides a nonsurgical approach to occlusion of such residual shunts. Provided that a site of stenosis is present within the shunt, successful coil occlusion can be expected.^{234–236} Hemolysis has been reported as a very rare complication of the procedure if high-velocity flow persists through the coiled shunt.

Arteriovenous Fistulas

Coronary artery fistulas can be effectively treated using transcatheter coil occlusion techniques.^{246–248} The technique requires a high degree of skill and knowledge of coronary

artery anatomy and catheterization techniques. Coronary artery fistulas may arise from the left or right coronary artery and communicate with the right atrium, right ventricle, or pulmonary artery. Coil occlusion has been most successful in treating such fistulas when a single large arterial feeder is present. Embolization can be performed using Gianturco coils or the smaller platinum microcoils. Coils can be delivered transvenously, but the transarterial route has been more commonly used. Complications may include incomplete occlusion with residual shunting, myocardial ischemia if a more distal coronary artery is inadvertently occluded, and distal embolization of a coil to the right heart or pulmonary artery, requiring retrieval. Late recanalization or endarteritis has not been reported after coil embolization of coronary artery fistulas.

Transcatheter coil embolization has also been used to treat intrapulmonary arteriovenous malformations.^{249,250} Such intrapulmonary vascular fistulas can be hereditary or may be acquired following a Glenn procedure or a modified Fontan operation. When intrapulmonary right-to-left shunting is significant, therapy is indicated to improve systemic arterial oxygen content. The catheter occlusion procedure may require implantation of numerous coils to effectively relieve hypoxemia.

Anomalous Venovenous Connections

Children with a univentricular heart who have undergone a Glenn shunt (unidirectional or bidirectional) or a modified Fontan procedure may experience persistent or recurrent arterial hypoxemia as a manifestation of anomalous venovenous connections. Such vascular communications provide a site for right-to-left shunting and decrease the volume of effective pulmonary blood flow. Transcatheter coil occlusion of undesirable venovenous shunts may therefore be indicated.³⁹ Examples of venovenous connections in a child with a bidirectional Glenn shunt include retrograde flow through the azygous vein or hemiazygous vein to the inferior vena cava or retrograde flow to the right atrium through a persistent left superior vena cava. In children with a Fontan procedure, right-to-left venovenous shunting may occur as the result of vascular communications between the inferior vena cava and the pulmonary venous atrium, particularly in children whose hepatic veins are excluded from the Fontan pathway.

Indications for Coil Occlusion

- I. Conditions for which there is general agreement that coil occlusion is appropriate:
 - a. Aortopulmonary collaterals with dual supply
 - b. Small PDA (diameter less than 4 mm)
 - c. Surgical aortopulmonary shunts
 - d. Intrapulmonary arteriovenous fistulas
 - e. Anomalous venovenous connections (post bidirectional Glenn or Fontan procedures)
- II. Conditions for which coil occlusion may be indicated:
 - a. Moderate PDA (diameter equals 4 to 7 mm)
 - b. Clinically silent PDA

c. Coronary arteriovenous fistulas

III. Conditions for which there is general agreement that coil occlusion is inappropriate:

- a. Aortopulmonary collaterals without dual supply
- b. Nonrestrictive PDA

Endocarditis Prophylaxis Issues

The AHA does not recommend routine antibiotic prophylaxis for cardiac catheterization.²⁵¹ Bacteremia is rarely observed during diagnostic cardiac catheterization,²⁵² and endocarditis after pediatric cardiac catheterization is rare.^{42,253} One report showed that in 575 children with infective endocarditis (pooled data from 11 series of studies), eight cases (1.4%) were related to previous cardiac catheterization.²⁵⁴ Trauma to the endothelium of a valve or endocardium during catheterization can induce deposition of platelets and fibrin, which leads to a nonbacterial thrombotic endocardial lesion, making the site vulnerable to infection. In addition, a congenitally abnormal structure within the heart or great vessels provides a site that could become infected. Without associated bacteremia, however, endocarditis will not occur. This points to the need for strict attention to sterile technique at the wound entry site.

Sporadic cases of endocarditis in children and adults have been reported after valvular or aortic coarctation balloon dilation procedures.^{255–259} According to Kulkarni et al,²⁵⁶ over a 4 1/2-year period endocarditis was reported in 3 of 195 (1.5%) mitral valve balloon dilations. The authors listed possible factors contributing to bacteremia as prolonged procedure times, multiple catheter exchanges, and reuse of accessories. Patients with abnormal heart valves or coarctation of the aorta are at risk for endocarditis during certain dental and surgical procedures likely to cause a bacteremia with an organism likely to cause endocarditis.²⁵¹ Balloon dilation procedures do not render the anatomic defect normal, so the patient remains at risk for endocarditis after an interventional procedure. Therefore, for children who have had valvuloplasty or balloon dilation of an aortic coarctation, the same recommendations for bacterial endocarditis prophylaxis should be observed before and after the procedure.

With regard to placement of intracardiac and intravascular prosthetic devices such as stents, coils, buttons, umbrellas, or other occlusive devices, investigators administer a short course of perioperative antibiotics, usually with a cephalosporin.^{26,95,103,260–264} Most specialists in the developing field of interventional cardiology suggest prophylaxis before certain dental and surgical procedures for 6 months after placement of such devices to allow endothelialization of the device.

When closure of defects such as ASDs, VSDs, and PDAs results in any form of residual shunting, continued antibiotic prophylaxis is indicated as in the preprocedure state. Guidelines for prophylaxis have been developed by the AHA²⁵¹ (Tables 1 and 2).

TABLE 1. Prophylactic Regimens for Dental, Oral, Respiratory Tract, or Esophageal Procedures

Situation	Agent	Regimen
Standard general prophylaxis	Amoxicillin	50 mg/kg PO 1 h before procedure (not to exceed 2 g)
Patient unable to take medications	Ampicillin	50 mg/kg IM or IV within 30 min before procedure (not to exceed 2 g)
Patient allergic to penicillin	Clindamycin	20 mg/kg PO 1 h before procedure (not to exceed 600 mg)
	or	
	Cephalexin* or Cefadroxil*	50 mg/kg PO 1 h before procedure (not to exceed 2 g)
	or	
	Azithromycin or clarithromycin	15 mg/kg PO 1 h before procedure (not to exceed 500 mg)
Patient allergic to penicillin and unable to take oral medications	Clindamycin	20 mg/kg IV within 30 min before procedure (not to exceed 600 mg)
	or	
	Cefazolin*	25 mg/kg IM or IV within 30 min before procedure (not to exceed 1 g)

IM indicates intramuscular, and IV, intravenous.

*Cephalosporins should not be used in persons with immediate hypersensitivity reaction (urticaria, angioedema, or anaphylaxis) to penicillins.

Acceptance and Approval Status of Therapeutic Catheterization Procedures: Implications for Usage

Investigational Devices and Procedures

FDA Investigational Device Exemption Usage

The *only* way for a new catheter or device to be officially accepted in the United States is through an FDA IDE protocol to determine safety and efficacy for human use. Such trials are for a specific use of a catheter or device and must be carried out for the new catheter or device to be used in humans. This is the approval route for most devices designed specifically for congenital lesions.

Approval Procedures

Remarkably few devices are officially approved for pediatric or congenital use. In fact, there is no organization to approve or sanction any interventional cardiac catheterization *procedure*. The FDA is responsible for initially assuring that drugs or devices are safe and effective for human use, but only a physician can determine exactly how a catheter or device should be used. Once approved for human use, how, when, and where it is used is a professional medical decision.

Only four FDA-approved devices are used in interventional procedures performed in the pediatric and congenital popula-

tion. The Rashkind balloon septostomy catheter and the Park blade septostomy catheter went through prospective but non-randomized, noncontrolled trials before FDA approval in the 1960s and 1970s, respectively. The data from the voluntary registry of the Mansfield polyethylene balloon for pulmonary valvuloplasty were accepted in the 1980s by the FDA to grant approval specifically for that balloon to be used only for pulmonary valve dilation in 1996. This was the first device approved for nonemergency use in patients with congenital heart disease. Subsequently a new noncompliant balloon was approved for the balloon atrial septostomy procedure. All of these devices have been effective, and the three septostomy devices are still in use but only account for a very small percentage of the many interventional or therapeutic procedures performed in congenital heart patients.

The official way to gain approval for a new or different *use* of a catheter or device (for another procedure or another age group) that has already been approved for human use is to proceed through an FDA IDE protocol. This route for every new use of devices previously approved for human use, unfortunately, would be equally as cumbersome and expensive as the basic IDE protocol and is unrealistic in the small pediatric and congenital population. This fact has led to the widespread, “off label” use of many devices that define current state-of-the-art practice.

TABLE 2. Prophylactic Regimens for Genitourinary/Gastrointestinal (Excluding Esophageal) Procedures

Situation	Agent(s)	Regimen*
Patient at high risk	Ampicillin plus gentamicin	Ampicillin 50 mg/kg IM or IV (not to exceed 2 g) plus gentamicin 1.5 mg/kg (not to exceed 120 mg) within 30 min of starting procedure. Six hours later, ampicillin 25 mg/kg IM/IV (not to exceed 1 g) PO.
High-risk patient allergic to ampicillin/amoxicillin	Vancomycin plus gentamicin	Vancomycin 20 mg/kg (not to exceed 1 g) over 1-2 h plus gentamicin 1.5 mg/kg IV/IM (not to exceed 120 mg). Complete injection/infusion within 30 min of starting procedure.
Patient at moderate risk	Amoxicillin or ampicillin	Amoxicillin 50 mg/kg (not to exceed 2 g) PO 1 h before procedure or ampicillin 50 mg/kg (not to exceed 2 g) within 30 min of starting procedure.
Moderate-risk patient allergic to ampicillin/amoxicillin	Vancomycin	Vancomycin 20 mg/kg (not to exceed 1 g) IV over 1-2 h. Complete infusion within 30 min of starting procedure.

IM indicates intramuscular, and IV, intravenous.

*No second dose of vancomycin or gentamicin is recommended.

Institutional Review Board Protocols

Within institutions, an alternative approach, particularly for a radical new use of an approved device, is to go through the institutional review board for approval of investigational use of an approved device. This is how individual pediatric cardiologists have used most new catheters or devices to establish a new procedure for pediatric and congenital patients within their center. Once the new procedure has been demonstrated as safe and effective by the investigating institution, the investigator reports the data. Others may then adopt the new procedure in their own institution, and with continued safe and effective use the procedure becomes generally accepted. This acceptance is not the same as a true FDA IDE approval for specific use but does establish a procedure as conventional therapy within the research community. This may not be the ideal method of developing new procedures, but with the relatively small prevalence of any particular congenital cardiac lesion, this is the only realistic way advances in catheter therapy can be accomplished for the pediatric and congenital populations.

This certainly is true for the use of new catheters, wires, or balloons for a previously accepted procedure. If every slight change in a catheter design required a new controlled study for use in pediatric patients, treatment of congenital heart disease would be stalled back in the 1940s or 1950s. In addition, physicians treating pediatric and congenital patients frequently benefit from developments of the very large adult cardiology and radiology markets and use many products developed and approved for atherosclerotic lesions in congenital lesions.

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KEY WORDS: AHA Medical/Scientific Statements ■ catheterization ■ pediatrics ■ defects

Correction

Re: the American Heart Association Scientific Statement entitled “Pediatric Therapeutic Cardiac Catheterization” (*Circulation*. 1998;97:609–625).

In the section on the buttoned device for closure of atrial septal defects (p. 611), the authors stated that “The device has not undergone a clinical IDE trial nor has it been approved by the FDA.” This is in fact incorrect. E.B. Sideris, MD, wrote to the authors:

“The buttoned device underwent the phase I FDA approved trial under an IDE between 1991–1992. Acute and follow-up results of this trial have been published (Lloyd TR, Rao PS, Beekman III RH, Mendelson AM, Sideris EB. Atrial septal defect occlusion with the buttoned device [a multi-institutional trial] *Amer J Cardiol*. 1994;73:286–291.) Three USA centers participated in the clinical trial. A phase II FDA approved trial is currently on the way in 5 centers and is approaching completion. It is possible that the buttoned device will be the first ASD occluding device to be ready for pre-market approval. Numerous hours were spent for the development of the method and the paperwork required for the 35 supplements sent to FDA so far; thousands of dollars have been spent in FDA-ordered testing.”

The authors apologize for this error. The electronic version of the paper, available on the AHA website (<http://www.americanheart.org/Scientific/statements/1998/029802.html>) has been corrected, and subsequent reprints will also reflect the change.