Initial Results and Medium-Term Follow-Up of Stent Implantation of Patent Ductus Arteriosus in Duct-Dependent Pulmonary Circulation

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| OBJECTIVES | This study was designed to assess the safety, efficacy, medium-term outcome, and compli- cations of patent ductus arteriosus (PDA) stenting in duct-dependent pulmonary circulation. | | | | |
|-------------|---|--|--|--|--|
| BACKGROUND | Patent ductus arteriosus stenting has been proposed as an alternative to surgical shunt on | | | | |
| | account of postoperative morbidity and complications of surgical shunting. | | | | |
| METHODS | Between April 2000 and February 2003, 69 patients with duct-dependent pulmonary | | | | |
| | circulation underwent cardiac catheterization with the intent of PDA stenting as first | | | | |
| | palliative procedure. Patients with critical pulmonary stenosis and pulmonary atresia with | | | | |
| | intact ventricular septum post-radiofrequency valvotomy who had PDA stenting were | | | | |
| | excluded. Thirteen more patients were excluded because of branch pulmonary artery (PA) | | | | |
| | stenosis. The follow-up was by clinical examination, echocardiography, and repeat cardiac | | | | |
| | catheterization at six to nine months following the procedure. | | | | |
| RESULTS | Patent ductus arteriosus stenting was successful in 51 patients (91.1%) and failed in 5 patients | | | | |
| REJUEIJ | (8.9%). The mean narrowest PDA diameter was 1.9 ± 0.6 mm. The mean procedure and | | | | |
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| | fluoroscopy time were 95.7 min and 29.4 min, respectively. In one patient the stent dislodged | | | | |
| | and migrated to the left femoral artery and another patient developed transient intravascular | | | | |
| | hemolysis. There was no procedure-related mortality. Three patients (5.9%) died one day to | | | | |
| | two months after the procedure. At follow-up (3.2 months to 2.4 years), 8 patients developed | | | | |
| | significant stent stenosis requiring reintervention. Seven patients developed worsening of | | | | |
| | preexisting branch PA stenosis. The freedom from reintervention was 89% and 55% at 6 | | | | |
| | months and 1 year, respectively. | | | | |
| CONCLUSIONS | 8 9 9 9 9 9 | | | | |
| | patients with duct-dependent circulation. An absolute contraindication to this technique is | | | | |
| | the presence of branch pulmonary stenosis. (J Am Coll Cardiol 2004;44:438–45) © 2004 | | | | |
| | by the American College of Cardiology Foundation | | | | |

Despite advances in surgical repair techniques of congenital heart diseases and a trend towards early primary repair, the surgical aortopulmonary shunt remains an important firststage palliation in duct-dependent cyanotic congenital heart disease. However, in neonates and small infants a surgically created aortopulmonary shunt is not without significant morbidity. Pleural effusion, diaphragmatic paralysis, cardiac failure due to excessive pulmonary blood flow, and distortion of branch pulmonary arteries are known complications that may compromise the feasibility or outcome of repair (1,2). Stenting of the patent ductus arteriosus (PDA) was thought to be a novel approach as an alternative first-stage palliation, but results of earlier reports have been discouraging (3,4). However, with improvement in coronary stent design and delivery systems, it is perhaps reasonable to reexamine the role of PDA stenting as an alternative to surgical aortopulmonary shunts.

The objective of stenting the PDA in our institution was to avoid or delay performing surgical shunts in neonates and young infants, in view of the higher postoperative morbidity in this group. This retrospective study was to assess the safety and efficacy of PDA stenting in cyanotic congenital heart disease with duct-dependant pulmonary circulation, as well as to evaluate the procedure's short- and medium-term outcome and complications.

METHODS

Between April 2000 and February 2003, 69 patients presenting for the first time with duct-dependent congenital heart disease underwent cardiac catheterization and angiography under general anesthesia with the intent of stenting the PDA as first-stage palliation. The majority of these patients presented to us between one and three months of age. Excluded from the study were 12 patients with pulmonary atresia with intact ventricular septum (PAIVS) and 6 patients with critical pulmonary stenosis (PS) in whom PDA stenting was part of right ventricle (RV) decompression procedure by radiofrequency valvotomy and balloon dilatation, or when the stenting was performed as additional procedure due to persistent severe cyanosis (SaO₂ <70%).

The detailed diagnoses were first established by twodimensional and Doppler echocardiography, categorizing the patients as having either single-ventricle or twoventricle physiology. Prostaglandin E1 infusion was stopped

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| Abbreviations and Acronyms | | | | | | | |
|----------------------------|---|--|--|--|--|--|--|
| BT | = Blalock-Taussig | | | | | | |
| LPA | = left pulmonary artery | | | | | | |
| PA | = pulmonary artery | | | | | | |
| PAIVS | = pulmonary atresia with intact ventricular | | | | | | |
| | septum | | | | | | |
| PDA | = patent ductus arteriosus | | | | | | |
| PS | = pulmonary stenosis | | | | | | |
| RF | = radiofrequency | | | | | | |
| RPA | = right pulmonary artery | | | | | | |
| RV | = right ventricle | | | | | | |
| TOF | = tetralogy of Fallot | | | | | | |
| VSD | = ventricular septal defect | | | | | | |
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6 to 12 h before stent implantation except in those who remained prostaglandin-E1-dependent, where it was discontinued at the commencement of the procedure.

Aortic arch angiography, mainly in anteroposterior, lateral, and four-chamber views, was performed to evaluate the PDA morphology and the state of the pulmonary arteries. The PDA origin from the descending aorta was noted, as well as its tortuosity and shape. The diameter at the PDA's narrowest point (usually its insertion into the pulmonary artery) as well as its length were measured. The presence of stenosis of the branch pulmonary artery at its takeoff or at the site of PDA insertion (pulmonary coarctation, Fig. 1) was also noted. Later in the study, as PDA stenting appeared to have worsened preexisting branch PA stenosis, patients with such abnormality (n = 13) were excluded from the study. Hemodynamic parameters such as arterial blood pressure and aortic oxygen saturation were also measured pre- and post-stent implantation.

Patent ductus arteriosus stenting was performed retrogradely in most patients via the femoral artery using a 4F long-sheath (Cooks Inc., Bloomington, Indiana). As most PDAs had their origin from the underside of the aortic arch, a 4F pigtail catheter with its loop cut to give an "inverted J" was used to engage the PDA ampulla. Patent ductus arteriosus that had a more normal orientation (arising from the descending aorta) or arose from the subclavian artery were easily engaged for guide wire anchoring with the 4F Judkins right coronary catheter. A 0.014" Choice PT coronary guide wire (Boston Scientific Scimed Inc., Maple Grove, Minnesota), which has a straight floppy tip but a stiffer body, was navigated across the PDA and anchored in a distal pulmonary artery branch or looped in the main pulmonary artery. Coronary stents were then implanted. In most ductus, the stent was implanted so that 2 to 3 mm of the stent protruded into the main pulmonary artery and the whole length of the ductus was covered up to the ductalaortic junction. The length of the stent chosen was 1 to 2 mm longer than the ductal length between the aortic and pulmonary end, with the guide wire across (as the guide wire tends to straighten a tortuous duct). Stents with a diameter of 3.5 mm were implanted in those weighing ≤ 3 kg, 4 mm stents in those weighing 3 to 5 kg, and \geq 4.5 mm in those weighing 5 kg and above. The stent types are summarized in Table 1.

In a small number of patients with tetralogy of Fallot (TOF)-pulmonary atresia where the PDA had a very proximal origin, stent implantation was performed anterogradely where a 6F Judkins Right or Left guiding catheter (Cordis Corporation, Miami, Florida) was passed from the venous side, across the ventricular septal defect, and into the ascending aorta.

Early in the series, only the distal half to two-thirds of the duct was stented in those patients with long tubular ductus that arose from the subclavian artery.

All patients were ventilated for at least 6 h and given heparin infusion at 25 units/kg/h for 48 h, followed by oral aspirin 5 mg/kg/day. Patients in whom PDA stenting was not attempted or unsuccessful were referred for modified Blalock-Taussig (BT) shunt. The follow-up was by clinical examination, echocardiography, and repeat cardiac catheterization at six to nine months (earlier if clinically indicated) post stent implantation

Statistical analysis. The SPSS statistical program for Windows, version 11.5 (SPSS Inc., Chicago, Illinois) was used to perform data analysis. Data was expressed as mean \pm SD, median (range), and frequency (percentage). The

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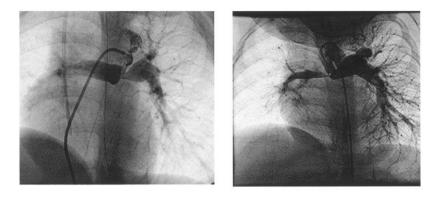


Figure 1. Pulmonary coarctation. (a) Left pulmonary artery stenosis; (b) bilateral branch pulmonary artery stenosis.

a

| Table | 1. | Types | of | Stents | Used |
|-------|----|-------|----|--------|------|
|-------|----|-------|----|--------|------|

| Stent Manufacturers | n | % |
|---|----|------|
| Jomed Jostent Flex Supreme System/Flex Master (JOMED GmbH, Rangendingen, Germany) | 24 | 47.1 |
| Express (Boston Scientific Scimed, Inc., Maple Grove, Minnesota) | 11 | 21.6 |
| Cordis J & J Bx Sonic/Bx Velocity (Cordis Europa N.V., Roden, The Netherlands) | 9 | 17.6 |
| Medtronic AVE S670 (Medtronic Inc., Minneapolis, Minnesota) | 3 | 5.9 |
| Others | 4 | 7.8 |
| Total | 51 | 100 |

difference in parameters before and after PDA stenting was examined using Wilcoxon signed-rank test. Probability of freedom from reintervention was determined by the Kaplan-Meier method. Reintervention was defined as either catheter-related intervention (balloon dilatation of stent, restenting) or BT shunt surgery. A p value of <0.05 was considered to be statistically significant.

RESULTS

Stenting of the PDA was attempted in 56 patients. The median age at the time of the procedure was 2.3 months (range 7 days to 2.8 years) and median weight was 3.9 kg (range 2.1 to 10.4 kg). Thirty percent of the patients were neonates. Two patients were <2.5 kg and eight patients were above the age of 1 year. Almost all of these older patients had TOF-pulmonary atresia with increasing cyanosis despite a previous BT shunt, and in two patients the pulmonary arteries were disconnected.

The patients were categorized as either having singleventricle physiology eventually destined for the Fontan track or two-ventricle physiology. The detailed diagnoses were as per Figure 2. In patients with single-ventricle physiology, PAIVS with hypoplastic RV and tricuspid atresia made up the largest number (64%), whereas in those with twoventricle physiology, TOF with pulmonary atresia formed the great majority (72%).

In 45 patients (88%), the PDA arose from underneath the arch proximal to the origin of the most distal branch of the arch. Most of these ductus formed a U-shaped curve

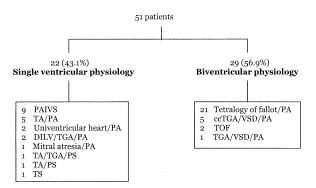


Figure 2. Diagnoses of patients who underwent successful stent implantation. ccTGA = congenital corrected transposition of great arteries; DILV = double-inlet left ventricle; PA = pulmonary atresia; PAIVS = pulmonary atresia with intact ventricular septum; PS = pulmonary stenosis; TA = tricuspid atresia; TS = tricuspid stenosis; TGA = transposition of great arteries; TOF = tetralogy of Fallot; VSD = ventricular septal defect.

before inserting into the pulmonary artery, and in five patients, they took a tortuous course with multiple loops. In four patients the ductus arose normally from the descending aorta and had a straight tubular course and in two patients the ductus arose from the subclavian artery, giving the appearance of a modified BT shunt (Fig. 3).

In five patients (8.9%), PDA stenting was not successful because of very proximal origin of the PDA from the aortic arch, or extreme tortuosity with multiple sharp bends, such that stable anchoring of the coronary guide wire in a distal pulmonary artery branch was not possible.

Of the 51 patients in whom PDA stenting was successful, in 43 patients (84.3%) the procedure was done retrogradely via the femoral artery, and in the remaining 8 (15.7%) this was done anterogradely (Fig. 4).

The mean PDA diameter at its narrowest part was 1.9 \pm 0.6 mm (range 0.6 to 2.9 mm) and mean length was 13.5 \pm 4.6 mm (range 4.8 to 24 mm). The great majority of stents implanted were of 4.0 mm and 4.5 mm diameter (94%). The mean stent length was $15.7 \pm 3.1 \text{ mm}$ (range 8 to 24) mm). In one patient, two stents were implanted in tandem to adequately cover the PDA length. The mean procedure time was 95.7 \pm 40.5 min (range 38 to 190 min) and mean fluoroscopy time was 29.4 ± 18.5 min (range 7.2 to 76 min). The aortic oxygen saturation increased from a mean of $70.1 \pm 14.2\%$ to $90.5 \pm 7.3\%$ (p < 0.0001) and the PDA diameter increased from a mean of 1.9 \pm 0.6 mm to 4.2 \pm 0.7 mm (p < 0.0001) immediately following the procedure. The mean duration of ventilation post procedure was 1.7 days and the mean hospital stay was 5 days (range 2 to 41 days).

Mortality and complications. There was no procedurerelated mortality. In one patient the stent was dislodged from the balloon catheter and migrated to the left femoral artery. The stent was removed through a minor surgical procedure. Transient complete heart block, due presumably to the stiff catheter pressing on the atrioventricular node, occurred in one patient. None of the patients lost their femoral pulses.

A patient with mitral atresia and single ventricle developed severe cardiac failure and excessive pulmonary blood flow. The patient died on the following day post-stenting. A patient with trisomy-21 developed transient intravascular hemolysis due to mid-segment PDA that was resistant to expansion at maximum pressure, giving an hourglass appearance to the expanded stent. She subsequently developed

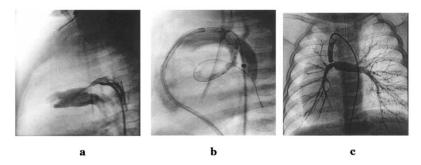


Figure 3. Morphology of arterial duct. (a) Ductus arising normally from descending aorta and has a straight tubular course; (b) "vertical duct" arising from beneath the aortic arch; (c) ductus arising from right subclavian artery.

Methicillin Resistant Staphylococcus Epidermidis septicemia and died at day 30. One patient with single-ventricle died in another hospital two months after discharge; the cause appeared unrelated to the procedure.

Follow-up. The mean duration of follow-up was 9.6 months (range 3.2 months to 2.4 years). The mean oxygen saturation at last follow-up was $79.2 \pm 5.2\%$. One patient in whom the PDA stent was completely blocked at three weeks postprocedure received a modified BT shunt.

Twenty-five of the surviving patients underwent repeat cardiac catheterization at 6 to 12 months post-stent implantation. In eight patients, the PDA flow became inadequate (oxygen saturation <70%) within six months post-stent implantation because of intimal proliferation (n = 6) and constriction of unstented segment of the PDA (n = 2) (Fig. 5). Two of these patients were destined for a single-ventricle repair (PAIVS, n = 1; tricuspid atresia with pulmonary atresia, n = 1) and the remaining six patients were those with TOF–PA (n = 2), congenitally corrected transposition of the great arteries with pulmonary atresia (n = 3), and transposition of the great arteries with ventricular septal defect and pulmonary atresia (n = 1). These patients were managed by constructing a modified BT shunt (n = 3), placement of additional stents (n = 2), and balloon dilation of stents (n = 3).

In seven patients preexisting branch PA stenosis (six in

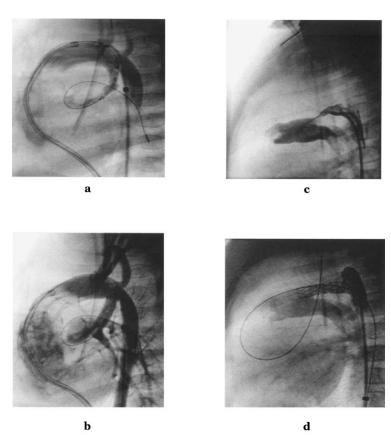
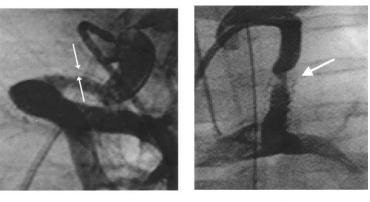


Figure 4. Transcatheter approaches of stent implantation. (a and b) pre- and post-stent implantation in tetralogy of Fallot-pulmonary atresia. A 6-F Guiding Judkin's Right catheter was passed through ventricular septal defect and anterogradely into ascending aorta with guide wire securely anchored in distal pulmonary artery; (c) normal ductus morphology in tricuspid atresia; (d) post-stent implantation by retrograde transarterial approach.



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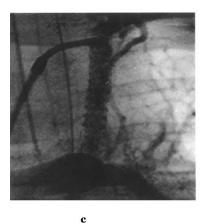


Figure 5. Stent stenosis. (a) In-stent stenosis: layer of neointimal proliferation between white arrows; (b) stenosis of unstented segment of a long vertical ductus arising from left subclavian artery; (c) an additional stent was implanted over the stenosed and unstented segment of the ductus.

left PA, one in right PA) became more severe and five of the patients were referred for surgical shunt on the affected side (Fig. 6).

Freedom from reintervention for the 51 patients was 89% and 55% at six months and one year, respectively (Fig. 7). Those patients less than three months of age had longer duration of ventilation and hospital stay. Freedom of reintervention was also lower in these patients compared with those more than three months old. At the last follow-up, two patients completed biventricular repair and one received bidirectional Glenn's shunt.

DISCUSSION

Despite the trend towards primary repair in the neonatal period or early infancy in the management of complex congenital heart diseases, the modified BT shunt remains an important first-stage palliation for many duct-dependent cyanotic lesions (5). However, in neonates this is associated with well-known morbidity such as diaphragmatic paralysis, pleural effusion, excessive pulmonary blood flow, and bronchopneumonia, leading to prolonged stay in the intensive care unit (1,2). In the subgroup of PAIVS patients who have severely hypoplastic RV and major sinusoids, modified BT shunts may be associated with low cardiac output and death, thought to be due to myocardial ischemia consequent to reduced diastolic pressure. In the series by Tamisier et al. (1) of 62 infants below three months who underwent BT shunts, there were 11 deaths among the neonates, of which 8 were patients with PAIVS or with univentricular heart.

Patent ductus arteriosus stenting seems a reasonable alternative to a modified BT shunt, as it eliminates the acute problems associated with a thoracotomy, and the long-term problem of scarring, which may render definitive repair difficult. Animal studies data have shown that the stented PDA has a reasonably good short- and medium-term patency, with neointimal proliferation being a limiting factor (4,6). However, results of an early report involving a small number of patients were not very encouraging (3,4). Major complications such as perforations of RV wall and pulmonary artery, dislodgement, or suboptimal position of stent were encountered. Furthermore, stent implantation was performed mainly through an axillary artery cutdown, which we felt was too invasive. It is perhaps for these reasons that PDA stenting remains marginal to modified BT shunt as a form of first-stage palliation. However, in

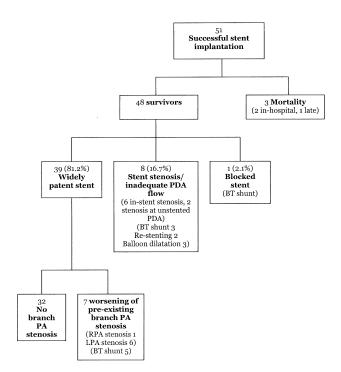


Figure 6. Outcome of 51 patients who underwent successful stent implantation. BT = Blalock-Taussig; LPA = left pulmonary artery; PA = pulmonary artery; PDA = patent ductus arteriosus; RPA = right pulmonary artery.

more recent reports the results were more encouraging (7,8). In these two studies, the patients were mainly those with critical PS and PAIVS who had already received definitive treatment in the form of balloon dilation with or without RF valvotomy, and PDA stenting was done transvenously as an additional procedure. In our series these patients were

excluded, as our objective was to look at the feasibility, complications, and outcome of PDA stenting as a nonsurgical alternative for first-stage palliation in duct-dependent pulmonary circulation. Furthermore, in PAIVS and critical PS patients in whom the right ventricular outflow obstruction is already opened with good forward flow, the stented PDA may rapidly thrombose off because of competitive flow, rendering analysis of the entire cohort difficult. In the Schneider et al. series (7), the subgroup of patients where PDA stenting was truly a first-stage palliation, stent delivery was via axillary artery cutdown or percutaneously via the femoral artery using significantly large sheaths (5F to 6F). With today's much improved coronary stent features such as flexibility, trackability, and heparin coating (9), aided by a variety of coronary guide wires and the use of 4F long sheathes via the femoral artery, we found that axillary cutdown can be avoided while preserving the femoral arteries. This approach was also used by Gewillig et al. (8) in two patients.

Technique. The PDA in cyanotic lesions, in particular TOF with pulmonary atresia, tend to have more proximal origin, have a curved tubular shape, and may sometimes take a tortuous course (10). This requires a cut pigtail catheter, giving it an inverted J-shaped tip to enable engagement of the PDA ampulla and guide wire navigation across the PDA, and finally to secure anchoring of the wire tip in a distal pulmonary artery branch. Once the stiffer part of the wire is across the PDA, it tends to render the ductus more horizontal and straight in orientation, enabling stent implantation with reasonable ease. In eight patients, all of them with TOF-pulmonary atresia, the PDA arose very proximally such that guide-wire anchoring in a distal pul-

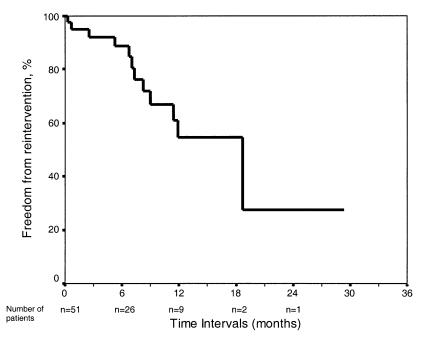


Figure 7. Freedom from reintervention. The reintervention included catheter-related procedure (balloon dilation of stent and restenting) and Blalock-Taussig shunt surgery.

monary artery branch was not possible. In such patients, stent delivery was done transvenously using 6F Judkin's Right or Left guiding catheter, which was passed through the VSD and anterogradely into the ascending aorta (Fig. 4). This was considerably more difficult compared to the retrograde technique.

In five patients the procedure was unsuccessful because the ductus had a very tortuous course with multiple sharp, acute angle bends, making it impossible to pass and anchor the guide wire.

Another important issue is to ensure that the entire length of the PDA is stented. Unstented segments of the PDA have a propensity for constriction. This was observed in two of our earlier patients who required additional stent implantation.

Branch pulmonary artery stenosis. It is not uncommon, particularly in TOF-pulmonary atresia, for the ductal tissue to cause branch pulmonary artery stenosis at its site of insertion ("pulmonary coarctation") (11,12). Early in the series we proceeded with stent implantation when the stenosis was mild (7 patients, all TOF-pulmonary atresia). We found that branch pulmonary artery stenosis was accelerated with PDA stenting and the patients required a modified BT shunt to salvage the stenotic branch pulmonary artery. The stent may have provoked an intense neointimal proliferation and fibrosis in the ductal tissues encircling the pulmonary artery wall. This condition has not been adequately highlighted and we feel that it is an absolute contraindication for PDA stenting in hearts with single ventricle destined for the Fontan track. It is therefore mandatory to angiographically evaluate the state of the pulmonary arteries before stenting the PDA, and the four-chamber view is useful in showing the pulmonary bifurcation and presence of branch PA stenosis at the site of ductal insertion.

Stent durability. The durability of the coronary stents is limited by thrombosis and neointimal proliferation (4,6,13). The newer heparin-coated and drug-eluting stents are designed to overcome these two problems (14). In our series, there was a reduction in oxygen saturation on follow up. In one patient (2.1%) the stent was blocked three weeks post implantation, probably due to thrombosis. Six patients had significant progression of the ductal flow restriction requiring reintervention within six months. This progression is probably due to accelerated neointimal proliferation. Our results were similar to those of Schneider et al. in that intimal proliferation leading to significant in-stent stenosis within six months is common, necessitating redilations (7). Inferior stent durability compared to conventional surgical shunt, among other factors, led Gibbs et al. (4) to conclude that PDA stenting cannot be recommended. However, with advances in pediatric cardiac surgery, a bidirectional Glenn shunt and Rastelli-type operations may be safely performed at four to six months (15-17); hence the inferior durability of a stented PDA may no longer be a major issue. Alternatively, the idea of a drug-eluting stent is attractive, but the

mechanism of in-stent stenosis in PDA is different from that of atheromatous coronary artery, and therefore this development may not necessarily prolong stent patency (14). Conclusions. With improved features of coronary stents and delivery system, as well as the use of 4F long sheath, maintaining ductal patency by percutaneous implantation of a stent offers a safe and feasible means of short-term palliation in neonates and young infants. Patent ductus arteriosus stenting, however, tends to worsen preexisting branch pulmonary artery stenosis at the site of PDA insertion, and its presence should perhaps be considered an absolute contraindication to PDA stenting in patients with single-ventricle physiology. Although PDA stenting tends to be less durable than conventional surgical shunt, this may not be a significant problem if definitive surgeries are performed at an earlier age and the restrictive duct can be redilated and restented. Cognizant of its limitations, we feel that PDA stenting is a reasonable alternative to surgical systemic to pulmonary arterial shunts in securing pulmonary blood flow in duct-dependent cyanotic heart disease and deserves further evaluation.

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