Published by Elsevier Inc.

ISSN 0735-1097/04/$30.00
doi:10.1016/j.jacc.2003.10.051

Interventional Catheterization Performed in the Early Postoperative Period After Congenital Heart Surgery in Children

Evan M. Zahn, MD, FACC,* Nancy C. Dobrolet, MD,* David G. Nykanen, MD,* Jorge Ojito, CCP,† Robert L. Hannan, MD,† Redmond P. Burke, MD†

Miami, Florida

OBJECTIVES The purpose of this study was to examine the safety and efficacy of interventional catheterization performed early after congenital heart surgery.

BACKGROUND Transcatheter interventions performed in the early postoperative period are viewed as high risk. To date, there have been limited published data regarding these procedures.

METHODS All catheterizations performed within six weeks after congenital heart surgery between August 1995 and January 2001 were retrospectively reviewed. A cardiac anesthesiologist, cardiac intensivist, cardiac surgeon, and operating room team were available for all cases. Interventional procedures were performed based on clinical indications, regardless of the time elapsed from surgery.

RESULTS Sixty-two patients, median age four months (2 days to 11 years), weight 4.7 kg (2.3 to 45 kg), underwent 66 catheterizations on median postoperative day 9 (0 to 42 days). Thirty-five cases involved 50 interventional procedures. Nine patients required extracorporeal cardiopulmonary support. Success rates by procedure were: angioplasty, 100%; stent implantation, 87%; vascular/septal occlusion, 100%; and palliative pulmonary valvotomy, 75%. Complications included stent migration (one patient), cerebral vascular injury (one patient), and left pulmonary artery stenosis (one patient). Thirty procedures involved angioplasty or stent implantation, including 26 involving a recently created suture line. Suture disruption or trans-mural vascular tears were not observed. There was no procedural mortality. Thirty-day survival for patients undergoing intervention was 83%.

CONCLUSIONS Transcatheter interventions can be successfully performed in the early postoperative period. These procedures can have a positive impact on patient outcome; however, they should be performed only by a pediatric interventional cardiologist supported by a multi-disciplinary team. (J Am Coll Cardiol 2004;43:1264–9) © 2004 by the American College of Cardiology Foundation

Over the last several decades, transcatheter interventions have become a mainstay in the treatment of children with congenital heart disease. The risk in performing these procedures is generally low, although certain interventions performed in selected patient populations are associated with an increased risk of complications and death (1–4). There is little published data regarding catheterization and transcatheter intervention performed on patients early in the postoperative period, especially the critically ill infant. Beginning in 1995, we adopted a programmatic philosophy that any child could safely undergo cardiac catheterization, regardless of the time elapsed from cardiac surgery or degree of illness, and that a variety of transcatheter interventions could be safely and effectively performed in this high-risk population. The purpose of this study was to examine the results of this approach.

METHODS

Study patients. Medical records and catheterization data of all patients undergoing catheterization <6 weeks after congenital heart surgery from August 1995 to January 2001 were reviewed. The decision to perform a catheterization and, subsequently, an intervention were made by a multi-disciplinary team including an interventional cardiologist, cardiac surgeon, and cardiac intensivist. Only patients in whom it was thought that delaying catheterization would prove detrimental to their clinical course were taken for early catheterization.

Technique. Cases were performed using general anesthesia in a bi-plane digital laboratory with the capacity to perform rapid table-side quantitative measurements, image enhancement, and dynamic road-mapping (Seimens, Hicor, Ehrlangen, Germany). A pediatric interventional cardiologist performed all cases with a cardiac intensivist, pediatric cardiac anesthesiologist, congenital heart surgeon, and operating room team in attendance or immediately available. For patients at exceptionally high risk, a cardiopulmonary support (CPS) unit was kept in the laboratory to allow for rapid initiation of cardiopulmonary bypass should it become necessary (5). Ventilatory, perfusion, and inotropic strategies were managed jointly by anesthesiology, cardiology, and when appropriate, a perfusion team. For patients requiring CPS, flow rates were lowered during angiographic injections and hemodynamic measurements to maximize diagnostic information. Vascular/septal occlusion proce-

From the Departments of *Cardiology and †Cardiac Surgery, Miami Children's Hospital, Miami, Florida.
Manuscript received January 24, 2003; revised manuscript received October 8, 2003, accepted October 20, 2003.

Abbreviations and Acronyms

CPS = cardiopulmonary support
ECMO = extracorporeal membrane oxygenators
mBTS = modified Blalock-Taussig shunt
PA = pulmonary artery

dures and palliative balloon pulmonary valvulotomies were performed using standard techniques (6,7). Newly created suture lines were crossed with high torque floppy-tipped guide wires in an effort to decrease the risk of suture line disruption. Completely occluded vessels and shunts were accessed with a hydrophilic guide wire (Terumo glide wire, Boston Scientific, Natick, Massachusetts) directed across the occlusion, followed by balloon angioplasty ± stent placement (Fig. 1). In general, stents with the largest potential ultimate diameter were used to allow for future expansion (Palmaz P188 and P308, Cordis, Miami Lakes, Florida). In selected neonatal cases, it was felt that these large stents and their accompanying rigid delivery systems presented too great a risk of suture line disruption/vessel rupture, and lower profile stent systems (Corinthian 124B, Palmaz P104, Cordis) were used. It was recognized that these stents have a maximum diameter of 12 mm and may eventually need to be surgically removed or enlarged; however, we decided that the critically ill nature of these infants justified this approach. In some cases, alternative vascular access was obtained surgically to facilitate catheter passage and stent placement. These included right and left carotid arterial cannulation as well as sheath placement directly into

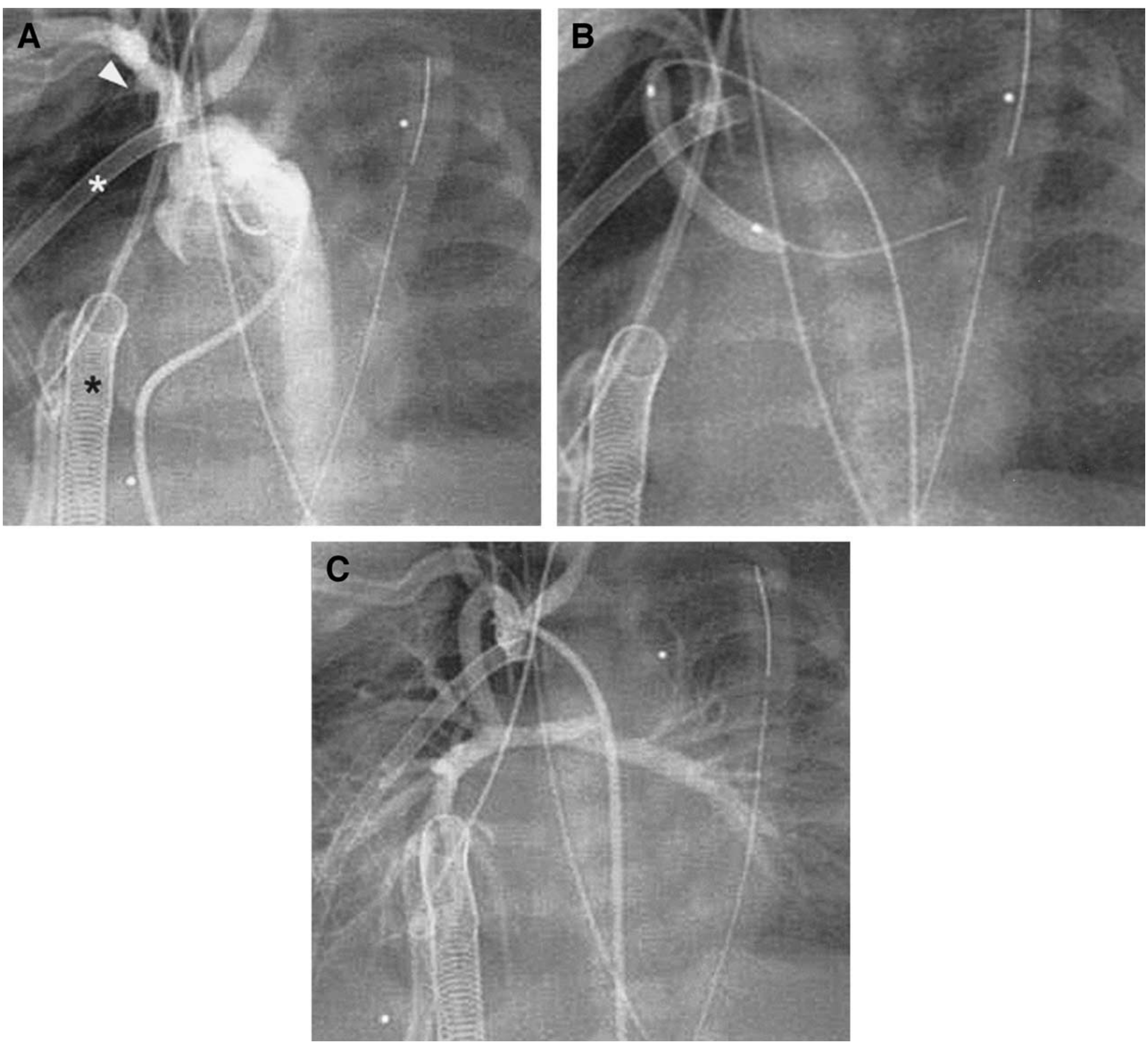

Figure 1. **(A)** Neonatal aortic angiogram performed 26 h after stage I palliative surgery for hypoplastic left heart syndrome shows complete occlusion of right modified Blalock-Taussig shunt (mBTS) **(white arrowhead)**. Note the venous **(black asterisk)** and arterial **(white asterisk)** cardiopulmonary support cannulas. **(B)** The occluded shunt has been crossed with a hydrophilic guide wire, and a 3.5-mm angioplasty balloon is inflated. Note the balloon is inflated across two recently created suture lines on either end of the mBTS. **(C)** Innominate artery angiogram after recanalization. The mBTS is patent, and there is no evidence of suture line disruption.

JACC Vol. 43, No. 7, 2004
April 7, 2004:1264–9

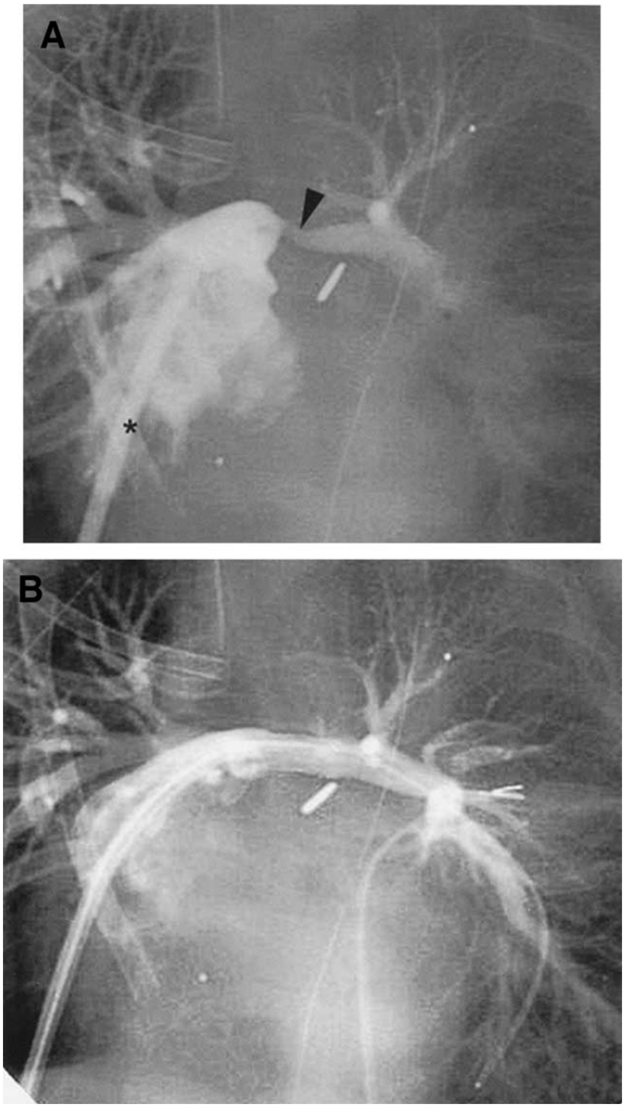

Figure 2. **(A)** Right ventricular angiogram performed via a sheath **(black asterisk)** placed directly into the right ventricular outflow tract (RVOT) via an open sternum in a four-month-old 6 h after RVOT reconstruction and pulmonary arterioplasty. Note the severe proximal left pulmonary artery stenosis **(black arrowhead)** at the anastomosis with the RVOT patch. **(B)** After stent placement, there has been complete relief of the stenosis without evidence for vascular disruption.

right ventricular pulmonary artery (PA) homograft conduits. These homograft sheath placements were performed in children with an open sternum to gain access to modified systemic PA shunts and branch PAs (Fig. 2). After stent implantation, sheath insertion sites were surgically repaired. After catheterization, all patients returned to a pediatric cardiac intensive care unit.

Table 2. Patient Demographic Data

Patient Variables	
Median age (months)	4 (2 days–11 yrs)
Median weight (kg)	4.7 (2.3–45)
Median time elapsed from surgery (days)	9 (0–42)
Mechanical ventilatory support	40/64 (63%)
Intravenous inotropic support	31/64 (48%)
Mechanical cardiopulmonary support	9/64 (14%)

Criteria for procedural success. Interventional procedures were considered as successful or unsuccessful based on previously published criteria (Table 1). In addition, due to the unique clinical indications for intervention in some of the patients, other clinical criteria such as the ability to separate from CPS within 24 h of the procedure and freedom from re-operation for cyanosis were considered indicators of success.

Statistical analysis. Arterial diameters before and after angioplasty or stent placement were compared using a paired *t* test. A value $p < 0.01$ was considered significant.

RESULTS

Sixty-six catheterizations were performed in 62 patients, median weight, 4.7 kg (2.3 to 45 kg); median age, four months (2 days to 11 years); and median time, nine days (0 to 42 days) from their last surgery. Demographic data and indications for catheterization are summarized in Tables 2 and 3. Patients requiring an intervention were catheterized at a median of six days after surgery. Seventy-one percent of these patients underwent catheterization <14 days after surgery and 91% <4 weeks after surgery.

Patient diagnoses and surgical procedures performed are listed in Table 4. At the time of catheterization, 61% were mechanically ventilated, 47% were receiving inotropic support, and 12% required mechanical CPS. While there was a wide range of diagnoses in this series, patients with single ventricle variants comprised nearly half (49%), followed by patients with pulmonary atresia, and ventricular septal defect or tetralogy of Fallot with hypoplastic PAs (22%). These two groups of patients required interventional procedures on a more frequent basis (single ventricle 56%, pulmonary atresia 92%) when compared with the remainder of the patients (22%).

In total, 50 interventional procedures were performed in 35 patients (Table 5). Success rates by procedure were: angioplasty, 100%; stent implantation, 87%; vascular/septal occlusion, 100%; palliative valvotomy, 75%. There was no procedure-related mortality. Thirty-day survival and sur-

Table 1. Criteria for Interventional Procedural Success

Interventional Procedures	Criteria for Success
Angioplasty/stent placement	Vessel diameter increase >75% adjacent normal vessel or 50% pre-dilation diameter or ability to separate from CPS within 24 h of the procedure
Vascular/septal occlusion	Absence of any significant residual flow as judged by angiography
Palliative pulmonary valvotomy	Freedom from reoperation for cyanosis

CPS = cardiopulmonary support.

Table 3. Indications for Early Post Operative Catheterization

Indications	n
Persistent/severe cyanosis	22
Low cardiac output state	12
Inability to wean from inotropic/ventilatory support	10
Inability to wean from cardiopulmonary support	9
Echocardiographic diagnosis of residual defects	9
Persistent/severe effusions (pleural/ascites)	4

vival to discharge was 83% and 80%, respectively, for patients requiring an intervention.

Thirty (60%) interventions involved either angioplasty or stent implantation. The majority of these (19 of 30) were performed <48 h after surgery including three patients who went directly from the operating room to the catheterization laboratory.

A total of 87% (26 of 30) of angioplasty/stent procedures involved recently created anastomotic sites, across a variety of native and prosthetic materials (Table 6). Balloon/stenosis ratio averaged 2.5 ± 0.9 (range, 1.4 to 4.4). Vessel diameter increased from 3.2 ± 2.9 mm to 5.9 ± 3.6 mm ($p < 0.001$). In no case was there evidence of suture line disruption, vascular rupture, or transmural tear.

Nine children underwent catheterization while requiring CPS. In all cases, a specially designed CPS circuit designed to facilitate rapid implementation and transport was utilized. The system features active venous drainage and heparin-bonded tubing, thus eliminating the need for gravity-dependent drainage and systemic anticoagulation. Five of these patients underwent interventional procedures including placement of PA stents (six patients), angioplasty of an occluded modified Blalock-Taussig shunt (mBTS) (one patient), right PA angioplasty (one patient), and coil occlusion of a large aorto-pulmonary collateral (one patient). There were no complications involving transport, catheter manipulation around CPS cannulas, or functioning

Table 5. Interventional Procedures Performed

Interventional Procedure	Number Performed
Angioplasty	
Pulmonary artery	10
IVC/SVC/Fontan baffle	2
Aorta	1
BTS	1
Innominate artery	1
Stent	
Pulmonary artery	9
IVC/SVC/Fontan baffle	3
BTS	2
Aorta	1
Vascular occlusion	
Aorto-pulmonary collateral	10
Venous collateral	2
PDA	2
LSVC	1
Palliative pulmonary valvuloplasty	4
Fontan fenestration occlusion	1
Total	50

BTS = Blalock-Taussig shunt; IVC = inferior vena cava; LSVC = left superior vena cava; PDA = patent ductus arteriosus; SVC = superior vena cava.

of the CPS unit during the catheterization. Six of nine (67%) patients successfully separated from CPS, and five (56%) survived to discharge. Two of the five intervention patients died shortly after separation from CPS after successful interventions. Both cases involved neonates with shunt-dependent pulmonary blood flow and complete occlusion or severe stenosis of the shunt. Neither child was able to separate from bypass, and both were maintained on CPS >24 h before adequate pulmonary blood flow was restored in the catheterization laboratory. One infant developed immediate and profound reperfusion pulmonary edema and pulmonary hemorrhage leading to death. The other continued to have diminished renal function and depressed cardiac function, which prevented successful

Table 4. Major Diagnostic Groups, Surgical and Catheterizations Procedures Performed

Diagnosis	Surgery	Diagnostic	Intervention	Total
PAVSD/TOF	RVOT reconstruction, VSD closure, PA angioplasty	1	12	13
Single ventricle variant	BDCPA	3	6	9
Single ventricle variant	Fontan	3	6	9
HLHS variant	Norwood I	4	3	7
Single ventricle variant	Modified BTS	4	3	7
Septal defect repair (ASD, AVSD)	Patch closure	4	0	4
PDA	Ligation	1	2	3
Aortic arch obstruction	Aortic arch reconstruction	4	2	6
TGA	Arterial switch	2	0	2
PAIVS	RVOT reconstruction	1	0	1
TAPVR	TAPVR repair	2	0	2
Aortic stenosis	Ross procedure	1	0	1
Subaortic stenosis	Konno procedure	0	1	1
TGA, PS, VSD	Modified BTS	1	0	1

ASD = atrial septal defect; AVSD = atrioventricular septal defect; BDCPA = bidirectional cavopulmonary anastomosis; BTS = Blalock-Taussig shunt; HLHS = hypoplastic left heart syndrome; PA = pulmonary artery; PDA = patent ductus arteriosus; PAIVS = pulmonary atresia/intact ventricular septum; PAVSD = pulmonary atresia/ventricular septal defect; PS = pulmonary stenosis; RVOT = right ventricular outflow tract; TAPVR = total anomalous pulmonary venous return; TGA = transposition of great arteries; TOF = teratology of Fallot; VSD = ventricular septal defect.

Table 6. Angioplasty/Stent Sites Involving Suture Lines

Material Involved	Number of Cases
Native vessel	8
Homograft tissue	7
ePTFE	6
Pericardial patch	5

ePTFE = expanded polytetrafluoroethylene.

weaning from CPS. Three major adverse events were noted. A single instance of stent migration occurred in a child requiring CPS who received two right PA stents. The more distal was placed uneventfully; however, the proximal stent migrated back into the main PA. This stent was surgically retrieved and replaced under direct vision using videoscopic guidance. Following this, the patient separated from CPS and was ultimately discharged home. There was a single cerebral infarction after stent implantation into an occluded mBTS via a percutaneous approach from the right carotid artery (previously published) (8). This patient arrived in the catheterization laboratory on significant inotropic support and receiving cardiopulmonary resuscitation. After stent placement, the patient recovered and was discharged from the hospital. Subsequently, steady neurologic improvement has been observed, and the patient has successfully undergone completion of a total cavopulmonary circulation. A third infant with a severe form of pulmonary atresia, ventricular septal defect, and multiple aorto-pulmonary collaterals who had undergone right ventricular outflow reconstruction was catheterized due to systemic hypotension and pulmonary over-circulation believed secondary to a large collateral. Transcatheter occlusion of the collateral resulted in markedly improved hemodynamics but left the patient with a moderate stenosis of the left PA secondary to protrusion of the coil into the lumen of the distal left PA. The patient was subsequently discharged and eventually underwent successful complete repair. Further intervention to correct the left PA stenosis is planned.

DISCUSSION

Interventional catheterization has become a mainstay in the treatment of many postoperative lesions such as branch pulmonary artery stenosis, conduit obstruction, and recurrent coarctation of the aorta. Improvements in catheter technology and techniques have allowed the application of many of these techniques to even the smallest of neonates (4). Despite these advances, it is our perception that transcatheter interventions at times may be avoided in the early postoperative period because they may be perceived to be associated with excessive risk. These perceived risks may include difficulties transporting these critically ill patients, concerns regarding worsening clinical status as a result of the procedure, and fear of disruption of recently placed suture lines (9). It is commonly thought that a minimum of six weeks must pass after cardiac surgery to allow for adequate formation of scar tissue around new anastomotic sites before an intervention can safely be attempted. There are, however, no studies to support this contention. This series reviews an experience with 66 consecutive catheterizations performed in children <6 weeks after heart surgery.

Multi-disciplinary team approach. Intuitively, the risk of catheterizing children early after surgery, particularly when they are critically ill, is higher than that of healthy children. Additionally, a large percentage of postoperative patients are neonates, a group known to be at increased risk for transcatheter intervention (4). In order to minimize risk, procedures in this series were performed using general anesthesia administered by a pediatric anesthesiologist experienced in congenital heart disease. This prevented airway compromise and greatly improved our ability to manage these critically ill, often unstable children. The presence of a pediatric cardiac intensivist and cardiac surgeon allowed for immediate medical and/or surgical intervention and consultation regarding the best treatment modality for a particular patient (catheter intervention vs. surgery vs. medical management). Surgical presence was also useful for clarifying postoperative anatomy, providing alternative routes of vascular access, managing CPS and standby should there be a significant surgical complication such as a vascular rupture. While this approach is labor intensive, the critical nature of these patients and the increased risk associated with early postoperative catheterization justifies it.

Angioplasty and stent implantation. One striking finding in this series was the absence of any identifiable suture line disruption, significant vascular tear, or death associated with angioplasty and/or stent placement. This contrasts with a report by Rosales et al. (9) where balloon angioplasty of the branch PAs in the early postoperative period was associated with a 20% mortality. The deaths in that study were believed to be secondary to vascular disruption with resultant bleeding. The balloon/stenosis ratio used was nearly identical to ours, making balloon size alone unlikely to be the reason for the reported deaths. It is possible that interinstitutional variations in surgical and/or interventional techniques may be responsible for the different outcomes. Additionally, the current study is more recent and may reflect the evolution of equipment and technique. It is possible that the presence of a cardiac surgical team with the ability to place patients on CPS quickly may have prevented some of the deaths described in that series.

Our experience suggests that a variety of freshly sutured materials can undergo angioplasty and stent implantation without resultant vascular disruption. There are several potential reasons for this. Suture lines were constructed of polypropylene monofilament (Prolene, Ethicon Inc., Summerville, New Jersey) sewn in a continuous fashion. Prolene can elongate as much as 34% before the breaking. In addition, there is an enlargement of the circumference of the suture line (increased distance between parallel throws) in response to balloon inflation, which prevents suture breakage within the limits of the angioplasties performed. We believe that continuous Prolene suture lines can be safely and effectively expanded with angioplasty using balloon/stenosis ratios ≤2.5/1.0. Because effective angioplasty often requires higher balloon/stenosis ratios, we agree with Rosales et al. (9) that, in many instances, stent placement is preferable to angioplasty in the early postoperative period. Additionally, by limiting recoil, stents ensure a more predictable and durable result. Unfortunately, some neonates may require implantation of small stents that will not accommodate an adult-sized vessel. Most of these children, however, will require future surgery, at which time the small stent can be enlarged or removed completely.

Catheterization of patients on mechanical CPS. Several reports have described the safety of performing pediatric cardiac catheterization in children maintained on extracorporeal membrane oxygenators (ECMO) (10–12). At our institution, we utilize a specially designed CPS unit that has many advantages over conventional ECMO (5). These include rapid setup time (5 vs. 45 to 60 min), elimination of requirement of blood prime, compact design, and minimal anticoagulation requirements (activated clotting time 180 to 220 s). These last two features are particularly beneficial in the early postoperative period where bi-plane imaging is often required and fresh incisions and open chests often encountered. DesJardins et al. (10) reported on 15 patients who underwent catheterization on ECMO over a five-year period including four interventions. All patients survived the procedure, and there was only one complication, a significant retroperitoneal bleed. Survival, however, was poor, with only 50% surviving decannulation and 29% to discharge. In contrast, the survival rates in our patient group were 67% to decannulation and 56% to discharge. Although the number of patients in both series is small, the differences in survival may be attributable to the greater rate of intervention performed in our patients (56% vs. 26%). In addition, the decision to utilize CPS may differ between programs. In the current series, where CPS was readily available as a treatment modality, the decision to utilize mechanical support may have been made earlier in the evolution of the patient's management. In retrospect, we believe that both deaths in our series, which occurred after successful intervention while on CPS, may have been related to delaying catheterization (both cases were performed after >24 h of CPS), thereby contributing to evolving neurologic, cardiac, renal, and pulmonary damage. Based on our experience, we now would advocate that patients who cannot separate form cardiopulmonary bypass after congenital heart surgery be converted to a CPS system and strong consideration given for early (<24 h) cardiac catheterization.

In conclusion, cardiac catheterization including intervention can be safely performed in the early postoperative period after congenital heart surgery. Angioplasty and stent placement can be safely and effectively accomplished across a variety of stenoses and recently created suture lines. A multi-disciplinary approach is necessary to achieve success.

Reprint requests and correspondence: Dr. Evan M. Zahn, Miami Children's Hospital, 3200 SW 60th Court, Suite 104, Miami, Florida 33155. E-mail: evan.zahn@mch.com.

REFERENCES

1. Vitiello R, McCrindle BW, Nykanen D, Freedom RM, Benson LN. Complications associated with pediatric cardiac catheterization. J Am Coll Cardiol 1998;32:1433–40.
2. Rhodes JF, Asnes JD, Blaufox AD, Sommer RJ. Impact of low body weight on frequency of pediatric cardiac catheterization complications. Am J Cardiol 2000;86:1275–8.
3. Cassidy SC, Schmidt KG, Van Hare GF, Stanger P, Teitel DF. Complications of pediatric cardiac catheterization: a 3-year study. J Am Coll Cardiol 1992;19:1285–93.
4. Simpson JM, Moore P, Teitel DF. Cardiac catheterization of low birth weight infants. Am J Cardiol 2001;87:1372–7.
5. Jacobs JP, Ojito JW, McConaghey TW, et al. Rapid cardiopulmonary support for children with complex congenital heart disease. Ann Thorac Surg 2000;70:742–9.
6. Goff DA, Blume ED, Gauvreau K, Mayer JE, Lock JE, Jenkins KJ. Clinical outcome of fenestrated Fontan patients after closure: the first 10 years. Circulation 2000;102:2094–9.
7. Sreeram N, Saleem M, Jackson M, et al. Results of balloon pulmonary valvuloplasty as a palliative procedure in tetralogy of Fallot. J Am Coll Cardiol 1991;18:159–65.
8. Zahn EM, Chang AC, Aldousany A, Burke RB. Emergent stent placement for acute Blalock-Taussig shunt obstruction after stage I Norwood surgery. Cathet Cardiovasc Diagn 1997;42:191–4.
9. Rosales AM, Lock JE, Perry SB, Geggel RL. Interventional catheterization management of perioperative peripheral pulmonary stenosis: balloon angioplasty or endovascular stenting. Cathet Cardiovasc Interv 2002;56:272–7.
10. DesJardins SE, Crowley DC, Beekman RH, Lloyd TR. Utility of cardiac catheterization in pediatric cardiac patients on ECMO. Cathet Cardiovasc Interv 1999;46:62–7.
11. Booth KL, Rothy SJ, Perry SB, del Nido PJ, Wessel DL, Laussen PC. Cardiac catheterization of patients supported by extracorporeal membrane oxygenation. J Am Coll Cardiol 2002;40:1681–6.
12. Ettedgui JA, Frieder FJ, Park SJ, Fischer DR, Siewers RD, del Nido PJ. Cardiac catheterization in children on extracorporeal membrane oxygenation. Cardiol Young 1996;6:59–61.