# Modified Blalock-Taussig shunt versus ductal stenting for palliation of cardiac lesions with inadequate pulmonary blood flow

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**Objective:** The modified Blalock-Taussig shunt is the most commonly used palliative procedure for infants with ductal-dependent pulmonary circulation. Recently, catheter-based stenting of the ductus arteriosus has been used by some centers to avoid surgical shunt placement. We evaluated the durability and safety of ductal stenting as an alternative to the modified Blalock-Taussig shunt.

**Methods:** A single-institution, retrospective review of patients undergoing modified Blalock-Taussig shunt versus ductal stenting was performed. Survival, procedural complications, and freedom from reintervention were the primary outcome variables.

**Results:** A total of 42 shunted and 13 stented patients with similar age and weight were identified. Survival to second-stage palliation, definitive repair, or 12 months was similar between the 2 groups (88% vs 85%; $P = .742$). The incidence of surgical or catheter-based reintervention to maintain adequate pulmonary blood flow was 26% in the shunted patients and 25% in the stented patients ($P = 1.000$). Three shunted patients (7%) required intervention to address contralateral pulmonary artery stenosis and 3 (7%) required surgical reintervention to address nonpulmonary blood flow-related complications. The need for ipsilateral or juxtaductal pulmonary artery intervention at, or subsequent to, second-stage palliation or definitive repair was similar between the 2 groups.

**Conclusions:** Freedom from reintervention to maintain adequate pulmonary blood flow was similar between infants undergoing modified Blalock-Taussig shunt or ductal stenting as an initial palliative procedure. However, a greater percentage of shunted patients experienced procedure-related complications and distal branch pulmonary artery stenosis. Palliative ductal stenting appears to be a safe and effective alternative to modified Blalock-Taussig in selected infants. (J Thorac Cardiovasc Surg 2014;147:397-403)



The modified Blalock-Taussig systemic-to-pulmonary shunt (mBTS) is the most commonly used palliative procedure for infants with ductal-dependent pulmonary blood flow. Although the mBTS generally provides a reliable and regulated source of pulmonary blood flow, patients remain at risk of early and late shunt occlusion.[1,2] Surgical shunt revision or catheter-based intervention to maintain or re-establish shunt patency has been required in a significant number of patients. In recent years, percutaneous transcatheter placement of a stent to maintain ductal patency has been used by some centers as an alternative method to provide a source of pulmonary blood flow.[3,4] The potential advantages of ductal stenting (DS) include reduced procedure-related risks, avoidance of cardiopulmonary bypass, and improved distribution of pulmonary artery blood flow. We reviewed our initial experience with DS as an alternative to mBTS in selected patients to determine the safety and effectiveness of this novel approach.

## METHODS

A retrospective review of patients who had undergone cardiac surgery or cardiac catheterization at Seattle Children's Hospital from December 2002 to April 2011 was performed after receiving approval from the hospital's institutional review board. During this period, 3,133 surgical procedures and 4,100 catheterization procedures were performed. A focused review of the medical records and procedure summaries was undertaken for 42 patients (median age, 12 days; range, 2-218) who had undergone placement of a mBTS and 13 patients (median age, 13 days; range, 4-43) who had undergone percutaneous implantation of a DS to maintain patency of the ductus arteriosus and provide a source of pulmonary blood flow. The patients who had undergone DS implantation as a part of a hybrid palliation (ductal stent plus balloon atrial septostomy plus bilateral pulmonary artery bands) for single-ventricle heart disease and the patients who had undergone placement of a mBTS and a concomitant cardiac surgical procedure, including pulmonary artery augmentation, were excluded from the present analysis. The patients who had undergone concomitant cardiac surgical procedures were excluded from the analysis because DS alone would not have been a realistic therapeutic option. The selection of

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**Abbreviations and Acronyms**
DS = ductal stenting
mBTS = modified Blalock-Taussig systemic-to-pulmonary shunt
STS = Society of Thoracic Surgeons

mBTS versus DS for each patient was individualized and determined by the estimated procedural risk, appropriateness of the pulmonary artery and/or ductus arteriosus anatomy, and patient comorbidities. The exclusion criteria for DS included discontinuous branch pulmonary arteries, an origin of either branch pulmonary artery from the ductus arteriosus, branch pulmonary artery stenosis, weight ≤2 kg (inadequate vascular access), and a concomitant need for cardiopulmonary bypass or an open surgical procedure. The tortuosity of the ductus arteriosus was not a contraindication. Data collection was terminated after second-stage palliation, definitive repair, or 12 months after mBTS or DS.

### Modified Blalock-Taussig Shunt

The procedure to construct an mBTS was performed as described by de Leval and colleagues.[5] Cardiopulmonary bypass was used in 8 patients (19%) who had exhibited hemodynamic instability or significant desaturation during the procedure. Heparin (100 U/kg) was administered before vascular exclusion and shunt placement in the patients who did not require cardiopulmonary bypass. The location and course of the shunt was determined by anatomic considerations, including aortic arch sidedness and the location of the ductus arteriosus. mBTS placement was performed through a median sternotomy in all patients. The mBTS was based on the right innominate or subclavian artery in 37 patients (88%) and the left subclavian artery in the remaining 5 (12%). The expanded polytetrafluoroethylene shunt diameter was either 3.5 mm (n = 13, 31%) or 4 mm (n = 29, 69%) depending on the size of the patient and the proximal branch pulmonary arteries. In the setting of a patent ductus arteriosus, concomitant ductal ligation was performed when adequate systemic saturation was observed after a brief period of temporary ductal occlusion. A patent ductus arteriosus was present in 26 of the 42 patients (62%), of whom 20 (77%) underwent concomitant ductal ligation. Primary sternal closure was performed at surgery in all patients.

### Ductal Stenting

Standard left and right heart cardiac catheterization was performed with the patient under general anesthesia and using femoral vascular access. The preferred stent deployment was in a prograde fashion using femoral venous access. In patients with pulmonary atresia and an intact ventricular septum, determination of right ventricular-dependent coronary circulation was performed. Percutaneous pulmonary valve perforation and subsequent prograde stent deployment was completed in the absence of right ventricular-dependent coronary circulation. Retrograde stent deployment was performed when the anatomic features prevented prograde deployment. Once vascular access was established, 3.5-mm (n = 1), 4-mm (n = 14), or combined 3.5- and 4.0-mm MULTI-LINK VISION (Abbott Laboratories, Abbott Park, Ill), premounted coronary stents were deployed within the ductus arteriosus. Patients received 1 (n = 4), 2 (n = 7), or 3 (n = 2) stents to establish adequate ductal patency. The stents were positioned such that 1 to 2 mm of stent material extended into the pulmonary artery confluence and beyond the ductal ampulla of the aorta. The ductal stents were placed such that approximately 20% to 30% of the stent was protruding into the aorta to prevent juxta-aortic ductal involution, which can lead to stenosis. Ligation of the stented ductus arteriosus was performed in 4 patients at definitive surgical repair or palliation. Ductal ligation alone was performed in 1 patient, and ligation and division of the ductus arteriosus was performed in 3 patients. Ductal ligation was performed with braided nylon suture, and the stented ductus was divided with scissors without difficulty. Mobilization and vascular control of the aorta were not necessary. When division of the ductus arteriosus was performed, the portion of the stent within the pulmonary artery was excised, and the small defect in the pulmonary artery was closed with a patch of autologous pericardium.

In the mBTS and DS groups, the primary indication for palliation was as follows: double outlet right ventricle in 7 (17%) and 0 patients ($P = .179$), tetralogy of Fallot in 7 (17%) and 1 (8%) patient ($P = .664$), pulmonary atresia in 12 (29%) and 8 (62%; $P = .048$), Ebstein's anomaly in 3 (7%) and 0 ($P = 1.000$), tricuspid atresia in 4 (10%) and 0 ($P = .562$), complex arterial transposition in 8 (19%) and 2 (15%; $P = 1.000$), and unbalanced atrioventricular septal defect in 1 (2%) and 2 (15%) patients ($P = .136$; Table 1).

The data are presented as the median and range or numbers and percentages. Statistical analysis of the categorical variables was conducted using Fisher's exact test. The groups were compared by unpaired $t$ tests for continuous variables. Survival analysis was performed using the Kaplan-Meier method, and a comparison of the survival curves was performed using the log-rank test. Analyses were performed using SPSS Statistics, version 19 (IBM, Armonk, NY), with $P < .05$ considered statistically significant. All reported $P$ values are 2-sided.

## RESULTS

No procedure-related deaths occurred in either group. The 30-day survival was 98% in the mBTS group and 92% in the DS group ($P = .371$). One mBTS patient died of irreversible bradycardia related to airway suctioning on the first postoperative day, and 1 DS patient died of multisystem organ failure on postprocedure day 5. The overall median follow-up was 189 days (range, 1-365; 196 days for mBTS vs 121 days for DS; $P = .347$). The overall survival to second-stage palliation, definitive repair, or 12 months was 87% (88% mBTS vs 85% DS, $P = .742$). During the 1-year follow-up period, second-stage palliation or definitive repair was performed in 27 patients (64%) in the mBTS group and 6 patients (38%) in the DS group ($P = .334$). The overall median interval to second-stage palliation or definitive repair was 189 days (range, 13-365; 198 days for mBTS vs 130 days for DS; $P = .197$; Table 2). The initial postprocedural systemic oxygen saturation was similar between the 2 groups (mBTS, 83%; range, 72%-97% vs DS, 87%; range, 68%-95%; $P = .077$).

An interval reintervention to maintain adequate pulmonary blood flow was performed in 11 patients (26%) in the mBTS group and 3 patients (25%) in the DS group ($P = 1.000$). The median interval to reintervention was 14 days (range, 1-121) in the mBTS group and 69 days (range, 4-146) in the DS group ($P = .287$). Multiple reinterventions to maintain adequate pulmonary blood flow were required in 3 mBTS patients (7%). No DS patients required >1 reintervention. Reintervention to maintain adequate pulmonary blood flow in the mBTS group included early surgical repair of tetralogy of Fallot with a transannular patch in 1, early bidirectional Glenn

**TABLE 1. Comparison of patients undergoing modified Blalock-Taussig shunt and ductal stenting**

| Variable | mBTS (n = 42) | DS (n = 13) | *P* value |
|---|---|---|---|
| Age (d) | 12 (2-218) | 13 (4-43) | .147 |
| Weight (kg) | 3.3 (2.3-8.6) | 3.3 (2.0-4.5) | .339 |
| Diagnostic indication | | | |
| Double outlet right ventricle | 7 (17) | 0 (0) | .179 |
| Tetralogy of Fallot | 7 (17) | 1 (8) | .664 |
| Pulmonary atresia | 12 (29) | 8 (62) | .048 |
| Ebstein's anomaly | 3 (7) | 0 (0) | 1.000 |
| Tricuspid atresia | 4 (10) | 0 (0) | .562 |
| Complex arterial transposition | 8 (19) | 2 (15) | 1.000 |
| Unbalanced atrioventricular canal | 1 (2) | 2 (15) | .136 |

Data presented as median (range) or n (%). *mBTS*, Modified Blalock-Taussig systemic-to-pulmonary shunt; *DS*, ductal stenting.

shunt placement in 1, balloon dilation of the shunt in 3, stenting of the shunt in 6, mBTS revision in 1, patent ductus arteriosus ligation in 1, and stenting of the central pulmonary artery in 1 patient. The indications for reintervention in the mBTS group included thrombotic occlusion of the shunt (n = 4) at 0, 0, 12, and 26 days, distal shunt narrowing (n = 3) at 14, 63, and 115 days, proximal shunt narrowing (n= 1) at 121 days, shunt distortion (n = 1) at 1 day, patent ductus arteriosus ligation (n = 1) at 47 days, and central (juxtaductal) pulmonary artery narrowing (n = 1) on the day of shunt placement. Juxtaductal narrowing of the right pulmonary artery appeared to be related to local distortion of the otherwise anatomically normal structure. Two patients in the DS group required placement of additional ductal stents, and one patient required mBTS on postprocedure day 69 because of complete occlusion of the ductal stent, presumably caused by ductal tissue neointimal proliferation. This patient subsequently underwent definitive surgical repair (Nikaidoh aortic translocation) 375 days later, without requiring mBTS reintervention. At second-stage palliation or definitive repair, 4 patients (15%) in the mBTS group required patch augmentation of the ipsilateral pulmonary artery and 2 (7%) required balloon angioplasty of the ipsilateral branch pulmonary artery within 30 days of repair. One patient (17%) in the DS group required patch augmentation of the juxtaductal proximal right pulmonary artery at placement of a Glenn shunt ($P = .488$). The actuarial freedom from interval reintervention was similar between the 2 groups (log rank test, $P = .914$; Figure 1).

**TABLE 2. Comparison of endpoint variables stratified by group**

| Variable | mBTS (n = 42) | DS (n = 13) | *P* value |
|---|---|---|---|
| 30-d Survival | 98 | 92 | .371 |
| Overall survival | 88 | 85 | .742 |
| Follow-up period (d) | 196 (1-365) | 121 (5-365) | .347 |
| Procedural complications | 3 (7) | 0 | 1.000 |
| Interval ipsilateral/juxtaductal reintervention | 11 (26) | 3 (25) | 1.000 |
| Interval to ipsilateral/juxtaductal reintervention (d) | 14 (1-121) | 69 (4-146) | .287 |
| Contralateral and/or distal intervention | 3 (7) | 0 | 1.000 |
| Ipsilateral or juxtaductal intervention at staged palliation or repair | 6 (22) | 1 (17) | .488 |

Data presented as %, median (range), or n (%). *mBTS*, Modified Blalock-Taussig systemic-to-pulmonary shunt; *DS*, ductal stenting.

Interventions to address clinically significant contralateral (juxtaductal) pulmonary artery narrowing were required in 3 mBTS patients (7%). Two patients required stenting of the contralateral branch pulmonary artery at 3 and 7 days after mBTS. Multiple percutaneous reinterventions were required to maintain adequate contralateral pulmonary artery flow in both patients. The third patient required left pulmonary artery patch augmentation at second-stage palliation. No patient in the DS group required an intervention to address distal, nonjuxtaductal narrowing. One mBTS patient (2%) required surgical exploration to address perioperative bleeding. Two mBTS patients (5%) required surgical wound exploration to address localized infection or deep mediastinitis. One patient in the DS group who required an mBTS to address complete stent occlusion developed a localized perioperative wound infection after mBTS placement. An additional DS patient experienced temporary femoral artery occlusion that responded to systemic heparin therapy. The vessel was patent at discharge, and the patient received 6 weeks of aspirin therapy.

Preoperative measurements of the branch pulmonary arteries were not performed before mBTS because preoperative angiography was not routinely performed at our institution. Angiographic pulmonary artery measurements obtained at the subsequent Glenn procedure or complete repair suggested that individual branch pulmonary artery

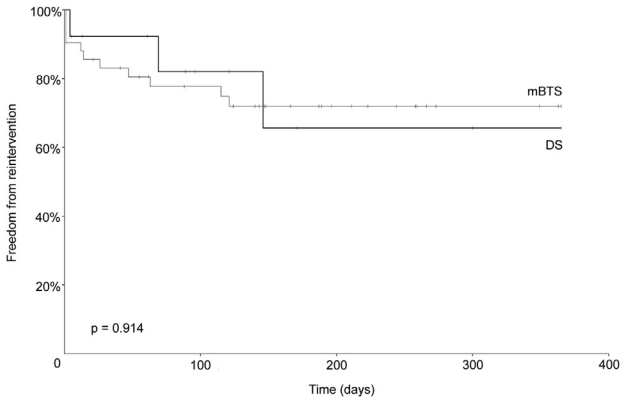


**FIGURE 1.** Kaplan-Meier curve comparing freedom from reintervention to maintain adequate pulmonary blood flow in patients receiving modified Blalock-Taussig systemic-to-pulmonary shunt (*mBTS*; *dark lines*) or ductal stenting (*DS*; *light lines*; $P = .914$).

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growth was not affected by ipsilateral mBTS placement (7.3 mm for the right pulmonary artery vs 7.7 mm for the left pulmonary artery; $P = .551$). Similarly, DS did not appear to discrepantly affect branch pulmonary artery growth (8.7 mm for the right pulmonary artery vs 8.0 mm for the left pulmonary artery; $P = .637$).

## DISCUSSION

Early primary surgical repair has been increasingly adopted in the treatment of neonates with congenital heart defects that include ductal-dependent pulmonary circulation and infants with inadequate pulmonary blood flow. However, the mBTS remains the most common palliative procedure for patients with complex intracardiac lesions and patients with inadequate right ventricular development who will proceed down a singe-ventricle (Fontan) pathway. Clinical data from >1,700 mBTS patients have been collected in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database since 2003,[6] with reported early survival approaching 93%.[7] In addition to the increased risk of perioperative mortality (approximately 33% of early deaths occur within 24 hours postoperatively), 11% to 13% experience perioperative morbidity.[1,7] Progressive shunt stenosis occurs in essentially all patients, with life-threatening shunt occlusion complicating the course of a small percentage.[1] Catheter-based interventions, including balloon angioplasty, stent implantation, and directed thrombolytic therapy, have been used to re-establish mBTS patency for decades, with an overall success rate of 90%.[8]

Introduced in 1992,[3] percutaneous stenting of the ductus arteriosus has been used by a number of centers to provide initial palliation for duct-dependent lesions[9] and as rescue therapy for late mBTS occlusion.[2] Compared with mBTS, evidence has shown that DS might provide a more evenly distributed pulmonary artery blood flow and promote more balanced growth of the pulmonary arteries.[9] Of the mBTS patients in our study, 3 required surgical or catheter-based interventions to address clinically important narrowing of the contralateral branch pulmonary artery. Although the narrowing appeared to be primarily related to involution of the ductal tissue within the pulmonary artery confluence, 2 of the patients required additional catheter-based interventions to address more distal narrowing that was remote from the ductal insertion site. Pulmonary artery narrowing remote from the ductal insertion site was not observed in any of the DS patients in our study, supporting the notion that the choice of mBTS or DS affects pulmonary artery development beyond the site of mBTS or DS insertion.

The overall reintervention rate in the present study was similar to the 21% overall early reintervention rate reported in a review by Yuan and colleagues[10] but greater than the 8% same-admission reoperation rate for mBTS patients reported in the STS Congenital Heart Surgery Database.[7] However, the data reported to the STS database have been limited to surgical reintervention only. Only 1 patient in the mBTS group underwent surgical reintervention during the same admission (2% early surgical reintervention rate), but 2 additional patients underwent early second-stage palliation (7% overall surgical reintervention rate). The decision to undertake surgical versus percutaneous reintervention to address shunt and pulmonary blood flow issues will undoubtedly be influenced by an individual institution's programmatic philosophy. An important limitation of the STS data registry is that it does not capture nonsurgical reintervention data, limiting the ability to perform comprehensive procedure-to-procedure comparisons. The median interval to reintervention (14 days) for the mBTS patients was similar to that reported by O'Connor and colleagues[11] (12 days). Although we observed a trend toward an earlier need for reintervention to maintain appropriate pulmonary blood flow in the mBTS patients, the reintervention rate was essentially the same for the 2 groups. Evidence has shown that the need for surgical or transcatheter reintervention to maintain mBTS patency is associated with significantly lower long-term survival.[11] Whether a similar association exists between reintervention and DS is unknown.

Although the present study was underpowered to demonstrate a significant difference in procedure-related complication rates, all the procedure-related complications occurred in the mBTS group. With all other outcome endpoints being similar, the observed trend toward increased procedure-related complications in the mBTS patients could become an important consideration in the choice of initial palliation for ductal-dependent lesions. Our patient selection strategy for DS was determined by echocardiographic evidence of confluent and adequately sized branch pulmonary arteries and catheter-based data regarding the presence of branch pulmonary artery stenosis. The tortuosity of the ductus arteriosus was not considered a contraindication to stent deployment. Patient selection bias was an obvious limitation of our study. However, our programmatic approach has generally been to perform DS in patients considered to be at increased risk of surgical complications. The use of DS in selected patients eliminates the risks associated with the use of cardiopulmonary bypass and reduces the risk of open procedure-related infection.

The mBTS remains the most common palliative procedure for lesions with ductal-dependent pulmonary circulation. Despite reduced usage of mBTS in recent years, increased operative survival has been observed in patients with increasingly complex cases.[12] The results of the present study suggest that DS is a safe and reliable alternative to mBTS for patients who might be at increased risk of surgical complications. Additional studies are needed to identify the anatomic and physiologic

characteristics to assist in appropriate patient selection. The results of the present study should provide surgeons and interventional cardiologists with a framework from which to explore alternative strategies for treating patients with ductal-dependent pulmonary circulation.

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## Discussion

**Dr Ross Ungerleider** *(Winston-Salem, NC).* Very nice. You are a cardiologist, right?

**Dr Rubio.** I am.

**Dr Ungerleider.** Give him the applause. It must take a lot of courage to come to a surgical meeting.

**Dr Rubio.** It is a little intimidating, but we will see.

**Dr Ungerleider.** Hang onto that courage right now. I have a couple questions for you.

It is interesting. If you put it in perspective, the Blalock-Taussig shunt was probably considered by many to be what started cardiac surgery, and then prostaglandins came along, and they took the word ''emergency'' out of shunting. Now cardiologists are coming along and might be taking the word ''surgical'' out of shunting. My first question for you really centers on that. We continue to evolve new methods to approach old problems, and we call this innovation. Although, as you mentioned, the concept of ductal stenting is not new, the application of ductal stents as a method to palliate patients who would more traditionally be treated with aortopulmonary shunts is a little bit novel. Now, without innovative thinking, we would just keep doing what we have always done and keep getting what we have always gotten; thus, I applaud you for this effort. However, philosophically and ethically, it does beg a question. When does innovation become human experimentation? More specifically, how did your patients give consent? Were they given surgical and interventional options? Did they know that this was a nonstandard option? Who did the consent process? Were the decisions made by the entire team, and, in fact, did you need to have institutional review board approval?

**Dr Rubio.** Thank you for the questions, Dr Ungerleider. The discussion about the option for an interventional approach instead of a surgical approach is a decision that is made in a general conference with consultation from the cardiothoracic surgeons, cardiologists, and interventional cardiologists. It is a team decision that is made, and that team decision is taken to the family as an option. The surgical reference standard, what I call the reference standard, the option of surgery for systemic to pulmonary arterial communication, is always the one presented first. Second, if other comorbidities are present that would make the patient a less than suitable candidate for bypass in case it might be needed, the discussion of a nontraditional—I do not like to use the word ''experimental,'' because this is not an experimental use, but rather the nontraditional use of coronary stenting, in this case stenting of the ductus—is given to the parents. Expectations are also given as to what type of follow-up will be needed.

**Dr Ungerleider.** I am just curious. Do you need institutional review board approval in your institution to do nonstandard therapy?

**Dr Rubio.** No, we do not.

**Dr Ungerleider.** The next question—you did so well, I am going to give you another one. This is more related to the indications for this. You did mention Gibbs' pioneering work in this, and, actually a member of this organization, Len Bailey, writing an editorial about that in 1999, heralded your work by calling this a ''wannabe'' Blalock-Taussig shunt. However, the prevailing thought at that time was that coronary stents were really not suited for the somewhat tortuous and anatomically more difficult ducti you see in the ductal-dependent lesions that are not hypoplastic left heart syndrome. You very nicely listed the potential complications of the Blalock-Taussig or aortopulmonary shunt. You did not really list them for ductal stents. Now you only had 13 or so—your numbers are small—but the complications or, as I like to call them, the consequences, of ductal stents have been well written. They have included malposition, restenosis, the need sometimes for multiple stents, erosion, the loss of vessels in the leg that might one day be necessary, and the technical demands. Those have been well described. Thus, the question I have for you really revolves around the important decision making as we enter this era of collaboration among cardiologists, interventional cardiologists, and surgeons, and you certainly seem to have a tendency to place these stents in patients with pulmonary atresia, so the question is, who are the patients who seem most suitable for this? Are they the patients with pulmonary atresia and a ventricular septal defect or those with pulmonary atresia and an intact septum? Tell us from your experience, as we start to consider this as an option, which of the patients would be the ones who we really should be thinking most about this?

**Dr Rubio.** With regard to the ideal patient for this, from my experience and the experience we have had at our institution, the

ideal patient is actually a patient with pulmonary atresia with an intact ventricular septum. These patients typically have a hypoplastic right ventricle. However, if they are able to demonstrate with echocardiographic evidence a tricuspid valve annulus that is <3 standard deviations away from the norm or we are able to delineate that there is a bipartite right ventricle, a pulmonary atretic valve that is reachable by cardiac catheterization safely, and an ability to establish prograde flow from the right ventricle into the pulmonary artery, we believe that those patients will be better candidates for prograde deployment of these coronary stents. Taking into account the many complications and quirks that these patients with pulmonary atresia have regarding their ducti, it does take a certain skill set to be able to be comfortable in deploying these stents. Stents have been deployed down the descending aorta. They have been deployed into the pulmonary valve. They have been known, if you are not careful, to exclude 1 of the branch pulmonary arteries. Vascular access is always a problem. Retrograde approaches are the most difficult and the ones associated with the most vascular occlusions. The prograde approach is not as complicated. Those would be the ideal patients.

**Dr Ungerleider.** It all sounds scary. I still like the idea of an outflow patch and a shunt. Thank you for sharing this. This is a very innovative technique that we will all pay attention to.

**Dr John Chen** *(Honolulu, Hawaii).* Dr Rubio, you should be congratulated on your excellent results, remembering that most of these patients, I presume, weigh $\leq$3 kg. I guess my question is have you followed up these patients or had the opportunity to follow-up these patients in the long term as to what happens to these shunts and have you come across a situation in which you had to ligate a shunt later on that had been stented? What do you do in that situation?

**Dr Rubio.** We have been able to follow-up a few of these patients in the long-term setting, meaning that they have reached about 1 year of age. In particular, a couple of the patients with pulmonary atresia and an intact septum in which the pulmonary valve was able to be perforated and allow for growth, the stents, when we are bringing them back into the catheter laboratory, have had a neointimal proliferation within the stent, which is a well-known complication. However, it has been auto-amputating itself, and the hope is that the natural course of this neointimal proliferation will begin to take the stent out of the equation of the additional pulmonary blood supply and not sacrifice significant saturation. The ligation I will have to leave to my surgeons, but it is common that, if we have to go to a Glen palliation at 6 months of age for a right ventricle that is not growing or if it is used in a patient who does not have the ability to have 2 sources of pulmonary blood flow, I do believe that the ductus is ligated with the stent in place. They crimp down the stent so that no further flow occurs.

**Dr Chen.** Ross, you just tie this thing off and crush the stent? What do you do with this?

**Dr Ungerleider.** You can crush them. They do erode sometimes. Usually, not that much flow occurs. What does happen, and it worries me, but any time we do new things, we have to be willing to accept the consequences of that. Anything we do has consequences. You might have to do some arch reconstructions in patients who would not ordinarily undergo an arch reconstruction, but for the most part, you can just crimp these stents. We have also cut through them sometimes when we are doing a Fontan for patients who have had stents in the pulmonary arteries. It is easy to cut through them, so they are there. Whether we should be putting them in this location or if we… . One of the points I would just say is, if we move to value-based care in which we are not being measured by relative value units but by what is the best we can do in using the resources, the real question we are going to be asking, because we will all get paid whether we do an interventional stent or a surgical shunt (the money comes in as revenue), and we want to make sure that we have value, more revenue, and less cost. The real question that we are going to be addressing one day is what is the best time to use these and which of the patients we should not use them for, but it is a very fascinating idea.

**Dr Gordon Cohen** *(Seattle, Wash).* As one of the surgeons who manages these stents, they are very easy to manage, as Ross said. We can just put a (ligate) clip across it, and if you are doing a bidirectional Glen as a second-stage palliation, it does not get in the way at all. It is just like ligating the ductus at the beginning of any other operation, but in these cases, we just use a ligate clip, and it is quite easy to deal with.

As far as Ross' questions go, if we think back to the history of the Blalock-Taussig shunts when Mark DeLaval first started doing the modified Blalock-Taussig shunt and using a Gore-Tex tube to do it, he did not have institutional review board approval. One day he had to make a decision that this was, in his opinion, a better operation, and it quickly became the reference standard. If we think about what the goals are in terms of doing a systemic to pulmonary shunt, really all we are doing is re-creating the ductus arteriosus. We cannot leave a patient taking prostaglandin for 6 months, so we are surgically re-creating the ductus arteriosus. In this case, we are just replacing the prostaglandin with a stent, and, frankly, it is very easy to manage. Also, what is nice about it is that when you come back for the second-stage operation, there is no risk of injuring the heart on re-entry; there are no adhesions to manage. If you want to use autologous pericardium to do a part of your reconstruction, it is easily available because it has not been adhered down to the heart. Thus, frankly, it makes everything very, very easy moving forward. The other point is, if you look in the Society of Thoracic Surgeons database, the outcomes from modified Blalock-Taussig shunts have not been so great. There is a pretty high mortality rate associated with it, and it is actually one of the higher mortality rate operations we do. This is a much less eventful procedure for the patient to undergo. They get the stent placed in the ductus. They tolerate it really quite well, and there is no big issue with it acutely. As Agustin presented to you, the long-term consequences are actually pretty easy to manage as well. I think in our institution actually we are moving toward it becoming, really, our primary intervention when a systemic to pulmonary artery shunt is needed.

**Dr Pranava Sinha** *(Washington, DC).* I congratulate you on the excellent outcomes of the ductal stent, which are much better than those in the previous reports in which there was a very high incidence of ipsilateral branch pulmonary artery problems.

I have 2 questions for you. One is, do you attribute this remarkable result to just pure patient selection or has advancement occurred in the technical aspect of the stenting? My second question to you is, in your abstract, I noticed an unusually long interval between stage 1 and stage 2—a mean of 245 days—which seems to be longer than usual. The longer you basically stay with a stent

or a shunt, the more complications you are going to see. Can you comment on that?

**Dr Rubio.** Regarding your first question, I think most of this is patient selection. We are very rigorous about choosing which patient would benefit best from ductal stenting. We are also very careful with deciding—it has occurred for some patients in the pulmonary atresia group that we have noticed that the ductus arteriosus insertion site is not at the bifurcation point but rather is more off to the right branch pulmonary artery or the left branch pulmonary artery, where you will have a significant issue with perfusion to 1 of the lungs. We are very careful with that. Usually, if that is the case, we see that on the first angiogram within the ductus arteriosus, and we refer those patients to surgery.

Regarding your second question, that was an observation we also made. We are not really sure why it was such a long time difference between stage 1 and stage 2.

**Dr Sinha.** Because I am looking at some data from our institution, and our median interstage interval has been in the range of 145 days.

**Dr Rubio.** There are certain patients that we, for geographic reasons—we cover Alaska and Montana and Idaho—we frequently do not get to them within the ideal time period that we would like because of extraneous issues that we have to deal with, so that skews some of the numbers, but I think for most of the patients, especially those undergoing single ventricle palliation, those patients are brought in in more of a standard time, with their second stage palliation occurring around 4.5 to 5 months of age. Our numbers are a little bit skewed also, because some of the patients have been able to potentially grow part of their right ventricle or have these 2 sources of pulmonary blood flow and remain stable, but it is something that we will be looking at in the future.