Efficacy of intraluminal pulmonary artery banding

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Objective: The extraluminal technique of pulmonary artery banding can be difficult to perform precisely in conjunction with cardiopulmonary bypass and is associated with a significant risk of band-related complications. We analyzed our results with an intraluminal technique of pulmonary artery banding in patients who required cardiopulmonary bypass for the performance of associated cardiac repairs.

Methods: The medical records of 18 neonates and infants who underwent intraluminal pulmonary artery banding were retrospectively reviewed. A circular patch with a 3.0-mm, 3.6-mm, or 4.0-mm diameter fenestration was sutured to the inner circumference of the main pulmonary artery. Preoperative, intraoperative, and postoperative variables were reviewed to assess the efficacy and safety of the intraluminal technique.

Results: Intraluminal pulmonary artery banding produced a consistent and significant reduction in the systolic pulmonary artery pressure (64.00 ± 12.24 to 16.53 ± 6.33 mm Hg, $P < .001$), the systolic pulmonary artery pressure/systolic systemic pressure ratio (0.91 ± 0.10 to 0.19 ± 0.07 , $P < .001$), and the pulmonary flow/systemic flow ratio (4.32 ± 3.04 to 0.91 ± 0.49 , $P = .015$). There were no band-related anatomic complications. Two patients did require percutaneous dilation of the intraluminal pulmonary artery band before debanding to palliate systemic arterial desaturation.

Conclusions: Intraluminal pulmonary artery banding is an effective palliative procedure that can be used in patients who require cardiopulmonary bypass for the performance of cardiac repairs in addition to placement of the pulmonary artery band.

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Advances in the surgical repair of congenital cardiac defects have resulted in a trend toward single-stage neonatal repairs and a reduced need for initial palliative procedures. Despite this, there remain rare indications for the performance of palliative pulmonary artery banding (PAB). Extraluminal PAB (EL-PAB) can be associated with significant complications and is difficult to perform in conjunction with cardiopulmonary bypass (CPB). When PAB is performed in conjunction with

associated procedures that require CPB, we find that intraluminal PAB (IL-PAB) is a reasonable alternative to EL-PAB for consistently and reproducibly limiting pulmonary blood flow with a low incidence of PAB-related complications.

Patients and Methods

Data Collection

The medical records of 18 neonates and infants with complex congenital cardiac disease who underwent IL-PAB at Children's Hospital of Michigan from 1993 through 2003 were retrospectively reviewed after obtaining institutional review board approval. Preoperative, intraoperative, and postoperative variables from both the banding and debanding procedures were collected.

Analysis

All data were entered and sorted in Microsoft Office Excel 2003 (Microsoft Corp, Redmond, Wash). These data were imported into SPSS for Windows (version 11.5.0; SPSS Inc, Chicago, Ill) for statistical analysis. Quantitative variables that approximated a normal distribution were reported as the mean $\pm$ SD and were analyzed by using the Student paired *t* test. Quantitative variables that did not approximate a normal distribution were reported as the median with a range and were analyzed by using the Wilcoxon signed-rank test.

Demography

There were 10 (56%) boys and 8 (44%) girls with a mean age at IL-PAB of 35 ± 32 days. The mean weight of the study subjects was 3.6 ± 0.83 kg, with a body surface area of 0.22 ± 0.03 m².

Cardiac Diagnoses

The cardiac diagnoses of the study subjects were grouped into 3 broad categories: (1) single-ventricle variants with unrestricted pulmonary blood flow and no evidence of systemic outflow tract obstruction at the subaortic, aortic annular, or ascending aortic levels (10 [56%] patients); (2) left dominant unbalanced complete atrioventricular canal defects (LD-CAVCs) with unrestricted pulmonary blood flow and questionable adequacy of the right ventricular volume (4 [22%] patients); and (3) miscellaneous cardiac defects with 2 balanced ventricles, unrestricted pulmonary blood flow, and a prohibitively high risk for primary complete repair because of severe associated cardiac defects and medical conditions (4 [22%] patients). The decision to place patients with LD-CAVCs in a category distinct from patients with an unequivocally univentricular heart was an arbitrary one. At the time of the banding procedure, it was believed that some of the patients with LD-CAVCs might eventually become candidates for a one-and-two-thirds ventricle repair,¹ as opposed to a complete Fontan palliation.

Clinical Presentation

Before the IL-PAB, 14 (78%) patients were hospitalized, with 12 (67%) of these being critically ill in the intensive care unit. Seventeen (94%) patients demonstrated symptoms consistent with congestive heart failure, including failure to thrive (12 [67%] patients) and tachypnea (11 [61%] patients). Six (33%) patients

Figure 1. A transverse incision is made in the anterior hemicircumference of the MPA. The fenestrated circular patch is sutured to the posterior wall of the MPA. The anterior MPA hemicircumference is closed by sandwiching the remainder of the patch between the edges of the MPA arteriotomy, thereby completing the fixation of the IL-PAB.

required preoperative mechanical ventilation. The median pre-banding systemic saturation was 89% (range, 66%-100%).

IL-PAB Surgical Technique

The surgeries were performed by 3 pediatric cardiac surgeons over the 10-year study period and represent all of the IL-PABs that have been performed at this institution. Cardiac exposure was obtained through a standard median sternotomy incision. The site for venous cannulation was chosen on the basis of the requirements for performance of the associated cardiac repairs. Direct cannulation of the superior and inferior vena cavae was performed if right atrial exposure, right ventricular exposure, or both was necessary. Otherwise, a single right atrial venous cannula was placed through the right atrial appendage. Varying degrees of hypothermia with reduced pump flow were used, as necessary, to optimize the exposure for performance of the associated cardiac repairs.

The IL-PAB was typically constructed toward the end of the operation during a rewarming period of full flow with a decompressed and perfused heart. A transverse incision in the anterior hemicircumference of the main pulmonary artery (MPA) 2 mm above the pulmonary valve commissures and proximal to the left and right branch pulmonary artery orifices was created. A circular patch of glutaraldehyde-fixed bovine pericardium (Peri-Guard Pericardium; Synovis Surgical Innovations, St Paul, Minn), photofixed bovine pericardium (Sulzer Carbomedics Cardiofix Peri-

TABLE 1. Concomitant procedures performed with intraluminal pulmonary artery banding

No.	Procedure
2	Atrial septectomy
4	Atrial septectomy; repair of hypoplastic arch; coarctation repair
3	Repair of hypoplastic arch; coarctation repair
1	Repair of interrupted aortic arch
3	Repair of TAPVC
4	Exploratory cardiomy
1	Exploratory cardiomy; epicardial pacemaker insertion

TAPVC, Total anomalous pulmonary venous connection.

cardium with Photofix Technology; Carbomedics Inc, Austin, Tex), or polytetrafluoroethylene (PTFE; Gore-Tex Cardiovascular Patch [0.6-mm thickness]; W. L. Gore & Associates, Inc, Newark, Del). was constructed with a diameter equal to that of the MPA. Care was taken to avoid significant oversizing of the diameter of the patch to avoid bulging of the patch into the orifices of the left or right branch pulmonary arteries. The patch was fenestrated with a 2.7-mm (2.7-mm punch; Scanlan International, St Paul, Minn), 3.6-mm, or 4.0-mm (3.5-mm and 4.0-mm punch; Genzyme Corp, Biosurgery, Fall River, Mass) circular punch, depending on the patient's weight and the judgment of the surgeon of record. In general, a 3.6-mm aperture diameter (11 [61%] patients) was chosen for patients weighing 3.0 to 3.5 kg. A 4-mm aperture diameter was usually constructed for patients weighing greater than 3.5 kg (5 [28%] patients). In 2 (11%) patients a 2.7-mm punch hole was enlarged to a 3-mm diameter aperture. The posterior hemicircumference of the fenestrated patch was then sutured to the luminal surface of the posterior hemicircumference of the MPA at a point opposite to the MPA by using a 5-0 or 6-0 Prolene (Ethicon, Inc, Somerville, NJ) continuous suture. The anterior hemicircumference of the patch was then sandwiched between the edges of the transverse pulmonary arteriotomy by using the same running suture. This closed the anterior pulmonary arteriotomy while completing the intraluminal fixation of the PAB (Figure 1).

The patient was weaned from CPB on 100% inspired oxygen and the inotropic support necessary to maintain an adequate cardiac output and saturations. After the discontinuation of CPB, the fraction of inspired oxygen was gradually reduced to maintain arterial saturations of 70% to 80%. Modified ultrafiltration was performed. The hemoglobin level was maintained in the range of 12 to 15 g/dL. Although the arterial saturations were frequently in the 70% to 79% range in the early postoperative period, they typically increased steadily over the ensuing 48 hours as the lungs recovered from the adverse effects of CPB.

Associated Surgical Procedures

Associated surgical procedures requiring CPB were performed on 17 (94%) of the patients undergoing IL-PAB (Table 1). This provided the opportunity to perform IL-PAB as a part of the required CPB procedure. Exploratory cardiomy to assess the feasibility of primary repair was the sole CPB procedure performed in conjunction with IL-PAB in 5 (28%) patients.

Pulmonary Artery Debanding Surgical Technique

During pulmonary artery debanding (PAD), the cannulation and conduct of CPB was identical to that during the IL-PAB procedure. When a cavopulmonary connection was performed in conjunction with PAD, the MPA was divided at the band site. The pulmonary valve leaflets and the proximal MPA stump were closed separately. The distal MPA was closed primarily. When a 2-ventricle repair or a one-and-two-thirds ventricle repair¹ was performed at the time of PAD, the transverse incision in the MPA was opened. The IL-PAB was excised, and the MPA was closed with a longitudinal and teardrop-shaped MPA patch extended into the anterior pulmonary sinus.

Results

Prebanding Echocardiographic and Catheterization Data

All patients had preoperative echocardiograms to document the anatomy and to establish the presence of unrestricted pulmonary blood flow. Eleven (61%) patients had a preoperative cardiac catheterization with cineangiograms to supplement the echocardiographic data. The systolic pulmonary artery pressure (S-PAP) in the catheterized group was 64 ± 12 mm Hg, and the S-PAP/systolic systemic pressure (SSP) ratio was 0.91 ± 0.1 . The pulmonary vascular resistance (PVR) was 4.0 ± 2.6 Woods units/m², and the median PVR to systemic vascular resistance (SVR) ratio was 0.25 (range, 0.10-0.58). The preoperative pulmonary flow/systemic flow ratio (Qp/Qs) was 4.3 ± 3.0 .

IL-PAB Operative Data

The CPB time was 81 ± 30 minutes, with a crossclamp time of 32 ± 22 minutes. The systemic saturation in the operating room at the end of the procedure was $80\% \pm 4\%$.

IL-PAB Hospital Course

The hospital mortality after IL-PAB and associated procedures was 22% (4 patients) and was attributable to associated profound medical problems. One patient with mitral atresia, obstructed total anomalous pulmonary venous connection, and double-outlet right ventricle (DORV) was receiving preoperative extracorporeal membrane oxygenation (ECMO) for profound respiratory failure. Postoperatively, he was maintained on ECMO for 10 days but was not able to be weaned because of persistent low cardiac output and pulmonary parenchymal disease. One patient with Down syndrome, LD-CAVC, coarctation of the aorta, and hypoplastic aortic arch died postoperatively of respiratory syncytial pneumonia and bacterial sepsis. One patient with a variant of hypoplastic left heart syndrome (HLHS) and multiple ventricular septal defects (VSDs) was given a preoperative diagnosis of anal atresia, necrotizing enterocolitis, syndrome of inappropriate antidiuretic hormone, renal failure, generalized hypotonia, and massive anasarca of unknown cause. The patient died of overwhelming bacterial sepsis and multisystem organ failure postoperatively. The final

patient was born at 33 weeks' gestation with CAVC, DORV, partial anomalous systemic venous connection, noncompacted left ventricular myocardium, congenital heart block, polysplenia, and persistent metabolic acidosis. This patient died of persistent low cardiac output postoperatively caused by preexisting myocardial dysfunction.

The discharge room air saturation of the hospital survivors was $84\% \pm 9\%$. The echocardiographically estimated IL-PAB gradient at hospital discharge was 65 ± 14 mm Hg. There was no evidence of pulmonary artery distortion, as determined on the basis of the discharge echocardiogram. The median length of stay of the 14 IL-PAB survivors was 8 days (range, 5-34 days).

Percutaneous Transcatheter Balloon Dilation of the IL-PAB Orifice

Two (11%) patients underwent successful percutaneous transcatheter balloon dilation of the IL-PAB aperture for low arterial saturations.

One 3.5-kg patient with mitral atresia–DORV and a 4-mm IL-PAB fenestration underwent balloon dilation of the IL-PAB aperture on postoperative day 3 after arterial saturations in the 60% to 69% range on high inspired fraction of inspired oxygen. He was extubated the following day and was discharged home on postoperative day 8 with room air saturations of 85%. When he returned for PAD and a hemi-Fontan procedure 5 months later at 6 months of age, his room air saturations and IL-PAB gradient were 79% and 59 mm Hg, respectively.

Another 4.5-kg patient with mitral atresia, DORV, and coarctation of the aorta–hypoplastic aortic arch and a 4-mm IL-PAB fenestration was discharged home with a room air saturation of 80% and an IL-PAB gradient of 86 mm Hg. She was readmitted 3 months postoperatively with room air saturations of 70%. Rather than proceed directly to PAD with the hemi-Fontan procedure, she underwent balloon dilation of the IL-PAB aperture. Her room air arterial saturations improved to 83% and remained stable until she underwent an uneventful PAD and hemi-Fontan procedure at 7 months of age.

Interval to Debanding (PAD)

Thirteen (93%) of the 14 IL-PAB survivors underwent PAD. One patient was lost to follow-up. The median interval from IL-PAB to PAD was 5.9 months (range, 3.7-12.4 months), and the mean age at PAD was 7.7 ± 2.3 months. The echocardiographically determined prebanding gradient was 82 ± 15 mm Hg. All 13 patients underwent cardiac catheterization with cineangiograms as a prelude to their PAD procedure. The directly measured IL-PAB gradient of the 13 catheterized patients who underwent PAD was 69 ± 17 mm Hg. Table 2 compares the prebanding S-PAP, S-PAP/SSP ratio, PVR, PVR/SVR ratio, and Qp/Qs ratio of the IL-PAB survivors who had a catheterization before the

TABLE 2. Prebanding and predebanding catheterization data

Value	Prebanding	Predebanding	P value
S-PAP (mm Hg)	64.00 ± 12.24	16.53 ± 6.33	$<.001^*$
S-PAP/SSP	0.91 ± 0.10	0.19 ± 0.07	$<.001^*$
PVR (WU/m ²)	3.96 ± 2.59	2.7 ± 1.54	.520*
PVR/SVR	$0.25 (0.10-0.58)$	$0.21 (0.08-0.32)$	.086†
Qp/Qs	4.32 ± 3.04	0.91 ± 0.49	.015*

S-PAP, Systolic pulmonary artery pressure; SSP, systolic systemic pressure; PVR, pulmonary vascular resistance; SVR, systemic vascular resistance; Qp/Qs, pulmonary to systemic flow ratio; WU, Wood units.

*Student paired *t* test (values expressed as means $\pm$ SD).

†Wilcoxon signed-rank test (values expressed as median with a range).

IL-PAB with the same values in those patients who underwent cardiac catheterization before their PAD. The IL-PAB produced a durable reduction of the S-PAP ($P < .001$), the S-PAP/SSP ratio ($P < .001$), and the Qp/Qs ratio ($P < .015$). Although the decrease in PVR was not statistically significant, the decrease in the PVR/SVR ratio did approach statistical significance ($P = .086$).

PAD Procedure

None of the patients who survived to the debanding procedure had any evidence of branch pulmonary artery distortion or pulmonary valve damage related to the IL-PAB. In all of the patients who underwent PAD, the MPA at the band site demonstrated a relative constriction related to the circumferential IL-PAB suture line and the fixed diameter of the IL-PAB.

The hospital mortality for the debanding procedure was 15.4% (2 patients). One patient with LD-CAVC underwent a hemi-Fontan procedure and died postoperatively of repeated bilateral branch pulmonary artery thromboses caused by a hypercoagulable state. The remaining patient was born weighing 2 kg with multiple VSDs, coarctation of the aorta, and hypoplastic aortic arch. She underwent an initial repair of coarctation of the aorta and hypoplastic aortic arch with IL-PAB. At her debanding procedure, a perimembranous VSD, a posterior muscular VSD, and an anterior muscular VSD were closed with 3 separate large patches. The pulmonary artery was debanded, and the main pulmonary artery was closed with a patch. She required postoperative ECMO because of intrinsic left ventricular dysfunction and died of persistent low cardiac output, despite maximal support.

Discussion

Extraluminal Technique of PAB

Coincident with advances in the early, complete, single-stage repair of congenital cardiac defects, there are now fewer indications for performing initial palliative procedures, such as PAB, than there were in the past.² PAB was

first reported by Muller and Dammann³ in 1952 in a patient with excessive pulmonary blood flow caused by a VSD. Since that time, many experimental and clinical techniques for the performance of PAB have been described in the literature. These proposed extraluminal techniques involve wrapping the MPA with (1) prosthetic band material that requires reoperation if postoperative adjustment is necessary,^{4,5} (2) prosthetic material and devices that can be adjusted percutaneously in the postoperative period,⁶⁻¹¹ (3) prosthetic material that can be balloon dilated in the postoperative period,¹²⁻¹⁵ (4) devices that can be adjusted remotely,¹⁶ and (5) absorbable prosthetic material.¹⁷⁻¹⁹

Intraluminal Technique of PAB

An intraluminal technique for performing PAB was first described by Doty and colleagues²⁰ in 1980 in a case report describing a palliative procedure for HLHS. In 1981, Behrendt and Rocchini²¹ described a similar technique for palliation for HLHS by using a fenestrated flap of native pulmonary artery to construct an intraluminal band within the pulmonary artery. Young and associates,²² in 1989, described the use of a fenestrated synthetic patch to construct an IL-PAB for palliation of 2 patients with truncus arteriosus. Parnell²³ responded in the same year with a letter to the editor describing his experience with an identical technique used to successfully palliate a patient with truncus arteriosus and tricuspid atresia. In 1999, Conte and coworkers²⁴ described the use of IL-PAB to successfully stage the complete repair of a patient with transposition of the great arteries, VSD, and a hypoplastic tricuspid valve and right ventricle. This present report is, to our knowledge, the first article to describe and analyze a series of patients with IL-PAB.

Indications for PAB

Although modern indications for the use of either extraluminal or intraluminal PAB are controversial, clinical situations in which PAB might be appropriate include (1) Swiss-cheese septum, (2) selected patients with multiple VSDs (other than Swiss-cheese septum), (3) patients with single-ventricle variants with unrestricted pulmonary blood flow and no existing (or impending) subaortic obstruction, (4) patients in need of left ventricular retraining, and (5) other miscellaneous conditions. Furthermore, some patients with congenital cardiac defects with excessive pulmonary blood flow that might otherwise be amenable to early and complete surgical repair might benefit from initial palliative PAB because of the presence of associated severe medical conditions that preclude safe primary repair. One such example is a severely premature infant with hyaline membrane disease, multiple VSDs, and ventilator dependency with failure to thrive, despite medical management. Although some indications still exist for the continued placement of

PABs, we believe that in general every effort should be made to use the technique sparingly. When, however, placement of a PAB is indicated in conjunction with the use of CPB, IL-PAB is a dependable and predictable surgical option.

Complications of PAB

In the present series of IL-PAB and in isolated case reports of various permutations of IL-PAB,²⁰⁻²⁴ there have been no anatomic complications attributable to the technique itself. On the other hand, a wide variety of complications have been reported with the use of EL-PAB techniques. Some of these include (1) branch pulmonary artery distortion,⁵ (2) erosion and migration of the band through the pulmonary artery wall,²⁵⁻²⁷ (3) sterile and mycotic pulmonary artery aneurysm formation at the band site,^{5,28} (4) pulmonary artery thrombosis,²⁹ (5) phrenic nerve palsy,⁵ and (6) vocal cord paresis.⁵

None of the IL-PABs in this series required reintervention for tightening. On the other hand, 2 patients undergoing IL-PAB did require percutaneous balloon dilation of the band aperture to treat systemic arterial desaturation. There were no complications related to these interventions.

Advantages of IL-PAB

Formulas for the placement of EL-PABs⁵ have proved helpful as starting points to estimate the appropriate initial band circumference. However, these formulas are only guidelines, and because of anatomic variations of the MPA between individual patients, they do not produce predictable MPA apertures. The EL-PAB circumference must be frequently adjusted to achieve the desired clinical result. Even after achieving an initially satisfactory result, there might be a period of internal MPA remodeling or distal band migration after placement of an EL-PAB. This can lower the initial EL-PAB gradient and necessitate reoperation to tighten the band.⁵ Placement of an EL-PAB in patients who have recently been weaned from CPB is especially problematic because the adverse effects of CPB on the pulmonary vasculature and parenchyma are added to individual patient variables to complicate the decision-making process involved in the placement of a satisfactory EL-PAB.

The major advantage of IL-PAB is in its application to situations in which CPB must be used for other cardiac procedures. It produces a predictable and reproducible band aperture, despite variations in patient anatomy and physiology and without producing anatomic complications, such as migration or internal remodeling, which might affect the band gradient. Because IL-PAB is an open technique performed with the pulmonary valve and branch pulmonary artery orifices under direct vision, injury or distortion of the pulmonary valve or branch pulmonary arteries is unlikely, especially when compared with extraluminal techniques.

In general, aperture diameters of 3.6 to 4.0 mm, depending on the patient's size, have produced satisfactory discharge band gradients (65 ± 14 mm Hg) with room air saturations of $84\% \pm 9\%$. These gradients have also been stable over time (69 ± 17 mm Hg, predebanding catheterization gradient). IL-PAB has also produced a reliable and durable reduction in the S-PAP, PAP/SSP ratio, and Qp/Qs ratio, thereby protecting the pulmonary vasculature and providing a satisfactory substrate for the performance of a second-stage repair later in life. Although the decrease in PVR has been less predictable, there is a trend toward significance in the decrease of the PVR/SVR ratio. None of the 2 deaths in the PAD group appeared to be related to increased PVR. IL-PAB is also readily amenable to percutaneous balloon dilation for treatment of systemic arterial desaturation should the IL-PAB aperture prove to be inadequate. This ability to percutaneously dilate the IL-PAB aperture is a distinct advantage over the usual extraluminal banding techniques.

Disadvantages of IL-PAB

Although IL-PAB is a more precise method for PAB, the requirement for CPB is a significant disadvantage when compared with EL-PAB. Although percutaneous balloon dilation of a tight IL-PAB aperture is a straightforward and effective advantage of this technique, tightening of an IL-PAB aperture would be a more complex undertaking requiring CPB. The intraluminal technique of PAB also increases the duration of CPB beyond that required for performance of the associated cardiac surgical procedures. Finally, there is a theoretic possibility of bleeding from the IL-PAB suture line in the MPA.

Conclusions

IL-PAB is precise, predictable, and effective as a palliative procedure to limit pulmonary blood flow in patients who require CPB for the performance of procedures additional to the PAB. Given the low rate of IL-PAB-related complications and the reliability of the procedure, serious consideration should be given to the use of this technique in preference to EL-PAB in patients requiring CPB.

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Discussion

Dr John Hawkins (Salt Lake City, Utah). I would like to commend Dr Piluiko and his colleagues at the Children's Hospital of Michigan for thinking outside the box here and challenging us to

basically present a new look at a way to perform what is an old procedure, namely PAB. I think, as Dr Shumway eloquently said this morning, that the best way to predict the future is to invent it, and therefore I always welcome articles that challenge our conventional wisdom of the way we do things.

I would just like to point out, as the authors did in the article, that this is actually a resurrection of an old technique on which one of our former presidents, Don Dody, reported back in 1980, when he discussed one of the very first successful neonatal palliations of HLHS, proving once again that there really is nothing new under the sun in cardiac surgery.

I think the authors have fulfilled the role of their title, namely that they have proved that this is an efficacious technique in that it decreased pulmonary artery pressure and Qp/Qs ratio and achieves what they set out to do, but I would have to say I still need to be convinced that this is something that we should be doing, and I have 3 questions that will give you a chance to try to convince me.

First of all, 10 of your 18 patients had single-ventricle variants, and 4 more had unbalanced forms of left ventricular dominant atrioventricular canal. These are patients who would, at many centers, be directed toward a Norwood type of procedure, at the very least perhaps oversewing of the pulmonary valve and a shunt. With the results for Norwood palliation in this day and age being 15% as a quite common mortality rate and in some centers even 5% or 10%, as we heard about this morning, an initial mortality rate of 22% and then a debanding mortality of 15% seems relatively high. How would you convince us that we should do what seems like a relatively risky procedure for a single-ventricle patient rather than perhaps in some centers performing a lower-risk Norwood palliation? I will let you answer these one at a time.

Dr Piluiko. Thank you, Dr Hawkins. None of the patients in the single-ventricle variant or unbalanced atrioventricular canal groups required a first-stage Norwood or Damus-Kaye-Stansel type of palliation because all of these patients had an adequate subaortic area, nonstenotic aortic valve leaflets, adequate aortic annular diameters, and adequate dimensions of the ascending aorta. As you mentioned, though, some of these patients could have been appropriately palliated by suturing closed the pulmonary valve leaflets and ligating or dividing the pulmonary artery with placement of a systemic-to-pulmonary artery shunt. It is not known whether this type of palliation is superior to PAB. As we will outline in detail in the article, we do not believe that the mortality in this series was related to the banding or debanding procedures per se but rather was clearly associated with profoundly serious associated medical and cardiac conditions that would predict a poor surgical outcome, regardless of the palliative scheme chosen.

Dr Hawkins. My second question is as follows. In Dr Doty's original article, the thing that got that particular patient in trouble was fibrointimal proliferation at the aperture of the fenestration in this internal band. Two of your patients required balloon dilation for cyanosis postoperatively, and therefore my question is this: At the time of reoperation for debanding, did you see any type of this fibrointimal proliferation in any of the 3 different types of materials that you used for the internal PAB?

Dr Piluiko. We did not see significant luminal fibrointimal growth at the debanding procedure in any of our patients. Given

enough time, pseudointima probably would develop on the IL-PAB prosthetic surface, irrespective of whether it is constructed of bovine pericardium or PTFE. However, for the period during which our IL-PABs were in place, this problem was not encountered.

Dr Hawkins. But even with the PTFE you did not see fibrointimal proliferation around this hole?

Dr Piluiko. For the time that these bands were in place, we did not see any significant fibrointimal growth in the lumen of the IL-PABs.

Dr Hawkins. One last quick question before we end here. I guess I would have to be a little bit cautious about adopting this, at least for me. I think some of the risks that you state are true for extraluminal PAB, mainly that it is difficult to adjust the band after bypass in those rare patients that need this. My question is, how do you adjust this after you have started bypass? If it is too much or too tight of a band or too loose of a band, it seems to me it would require CPB to make an adjustment, and some of the things that you say are the disadvantages of extraluminal banding are even more true for this.

Dr Piluiko. After placement of an IL-PAB, our patients are initially fairly cyanotic in the operating room. None of our patients, however, had to be placed back on bypass to either tighten or loosen the band acutely. Typically, the patient's saturations would increase gradually in the operating room and in the subsequent 1 or 2 postoperative days until they reached satisfactory discharge levels. In the one case in which a patient's saturation did not improve in the first few postoperative days, we successfully ballooned the band orifice. The other patient who, 3 months after banding, experienced a decrease in these saturations before the time at which we were comfortable performing a hemi-Fontan procedure also underwent a successful ballooning. We view the ability to loosen a tight IL-PAB nonoperatively as a virtue of this technique rather than a liability. None of our IL-PABs were loose, either acutely or remotely. Again, we view this consistent creation of an appropriately tight band as an asset of the technique. If, however, an IL-PAB did appear to be too loose and require tightening, this would require bypass to perform accurately. This would have to be considered a rare but theoretically plausible liability inherent in the IL-PAB technique. When compared with the many well-documented complications that can plague IL-PABs, we believe that the risk/benefit ratio of the intraluminal technique favors it over the extraluminal technique in cases in which bypass must be used for the performance of associated cardiac surgical procedures.

Dr Winfield Wells. (*Los Angeles, Calif*). I just want to really make more of a brief comment than ask a question. I think much of the problems with bands that you have reported took place when the banding material might not have been as ideally selected as it can be now. Actually, in using a silicone rubber material for a band, our experience is that the patients can be banded for 6 months or whenever you usually get to the next palliation for single ventricle and that the band can be slipped off and no augmentation of the pulmonary artery needs to be done. I would just comment that some of the new external banding materials in fact overcome many of the obstacles you have mentioned.

Dr Piluiko. Thank you for your comment.