Balloon Angioplasty for Obstructed Modified Systemic-Pulmonary Artery Shunts and Pulmonary Artery Stenoses

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OBJECTIVES
The results of percutaneous balloon angioplasty for obstructed modified Blalock-Taussig (BT) or central shunts and pulmonary artery (PA) stenoses were studied to assess its role as an alternative to second shunt and surgical PA angioplasty.

BACKGROUND
Obstruction of a modified shunt and PA stenosis related to the shunt or ductus are not infrequent. A second shunt with or without PA angioplasty is required if the PA size, morphology or age of the patient is suboptimal for definitive surgery.

METHODS
From June 1994 to May 1999, balloon angioplasty for obstructed systemic-to-PA shunts was performed in 46 patients, with ages ranging from 1 month to 7.4 years (2.2 ± 1.9 years). Among the 46 patients, 32 had modified BT shunts, 5 had bilateral shunts, 7 had modified central shunts, and 2 had both modified BT and central shunts. Stenoses were seen in 27 main branch PAs, and interruption was present in three. A concurrent balloon angioplasty was attempted in 28 main branch PAs, but it was performed in only 25 vessels.

RESULTS
Balloon dilation for obstructed modified shunts was considered to be effective in 42 patients (91%), while angioplasty for PA stenosis was effective in 14 vessels and not effective in 11 vessels. After balloon dilation angioplasty, oxygen saturation in the aorta increased from 74.4 ± 4.3% to 80.8 ± 3.6% (p < 0.01) in these 46 patients. One patient died of pneumonia. Eight patients required an additional modified BT shunt soon after the procedure because of severe stenosis or interruption at main branch PA. After a mean follow-up period of 11.6 ± 5.4 months, 29 patients underwent a repeated imaging study to evaluate the morphology and size of the PAs. Of these 29 patients, 26 underwent open-heart surgery, with two mortalities.

CONCLUSIONS
When a second shunt is under consideration because of obstruction of the modified shunt, balloon angioplasty is a possible alternative procedure. Pulmonary artery stenosis, if present, can be simultaneously dilated. (J Am Coll Cardiol 2001;37:940–7) © 2001 by the American College of Cardiology

Primary repair in many congenital heart anomalies among younger infants is on the increase. However, many patients in early infancy still require a palliative systemic-pulmonary artery shunt (1,2). The classic Blalock-Taussig (BT) shunt is a widely accepted palliation for certain forms of congenital heart disease where an increase in pulmonary blood flow is required. A modified BT shunt, performed by placing a polytetrafluoroethylene (PTFE) tube between the pulmonary artery (PA) and the subclavian artery, is increasingly common because it provides satisfactory long-term results with low morbidity (3–5). In some instances, a modified central shunt is employed to palliate certain forms of cyanotic heart disease (6). Occlusion or stenosis of a systemic-PF shunt is not infrequent (7–9) and may result in aggravated cyanosis. A second shunt may be required if the PA size, weight or age of the patient is suboptimal for definitive surgery. Balloon angioplasty for a stenosed classic BT shunt has been performed with varied success (10–14). However, reports of angioplasty for a systemic-PA PTFE shunt are relatively rare (15–17). This study describes the results of the dilation of obstructed PTFE shunts and simultaneous angioplasty for PA stenoses in patients with complex heart disease.

METHODS
Patients. The study protocol was approved by the human research committee of this institution. Over a 60-month period from June 1994 to May 1999, 70 patients in this institution were diagnosed with a stenosed modified systemic-PA shunt after cardiac catheterization and angiography. Of them, 21 patients were considered as candidates for definitive repair. The remaining 49 patients were judged to require another palliative procedure before definitive repair because of suboptimal PA size or suboptimal age. Attempts to dilate the stenotic shunt failed with three patients. Forty-six patients who underwent dilation of the obstructed PTFE shunt were enrolled in this study. Their ages ranged from 1 month to 7.4 years (2.2 ± 1.9 years, mean ± standard deviation). Their body weight ranged

See page 948

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from 3 to 18.1 kg (9.4 ± 4 kg). There were 29 boys and 17 girls. Two patients were intubated with ventilatory support. Seven patients required continuous infusion of PGE1 to maintain O2 saturation above 75%. Eight patients required continuous oxygen inhalation. Of the 46 patients, 32 had a modified BT shunt; 5 had bilateral modified BT shunts; 7 had a modified central shunt, and 2 had a modified BT shunt and a central shunt. The diameters of the shunts implanted ranged from 3.5 mm to 6 mm. Among the 46 patients, 24 had main branch PA stenosis, and three had interruption of a PA. Of the 24 patients with main branch PA stenosis, the stenosis was found in 27 main branch PAs: 12 juxtaductal stenoses, 4 long segment hypoplasia of central PAs, 9 shunt related stenoses and 2 multiple stenoses related to both shunt and ductus. Dilation of the stenotic lesions was attempted in 28 main branch PAs: 27 with stenosis and one with acquired interruption.

Methods. All except seven patients who were younger than two months received pre-medication with a cocktail of meperidine, promethazine and chlorpromazine 30 min before cardiac catheterization. The seven patients who were younger than two months were sedated with ketamine, valium or dormicum. After local anesthesia, the femoral vein and artery were percutaneously accessed. A 5F or 6F sheath was used for cannulation of the femoral vein or artery. Ketamine or dormicum was used as required. Heparin 50 U/kg was routinely administered. After hemodynamic studies, a selective angiogram at the distal subclavian artery was obtained by employing a balloon occlusion technique to delineate the site of obstruction in patients with a modified BT shunt. The narrowest diameter of the stenotic lesion in the modified BT shunt or subclavian artery was measured in each patient. An angiogram of the aortic root or descending aorta was performed on those with a central shunt. After subclavian arteriography or aortography, a right Judkins catheter (Cordis, Miami, Florida) or head-hunter catheter (Balt, Montmorency, France) was advanced to the PTFE graft. A soft tip 0.035 Radifocus guidewire (Terumo Corp., Tokyo, Japan) was then positioned in the PA through the 4F or 5F right Judkins catheter or head-hunter catheter. After retrieving that catheter, a low profile (5F) short taper balloon catheter (Schneider, Bulach, Switzerland) was advanced along the guidewire to the stenotic lesion. The balloon was inflated several times by applying a pressure of 3 to 8 atm. Each inflation lasted <10 s. For the sole patient with total occlusion of the shunt, a floppy tip 0.014 coronary guidewire was gently advanced along the occluded PTFE graft, and an ACS coronary balloon catheter (Advanced Cardiovascular Systems Inc., Temecula, California) was advanced to the shunt to perform angioplasty. Then, progressively larger balloon catheters were used to dilate the occluded shunt. Of the five patients with bilateral modified BT shunts, both shunts were dilated in two patients, and one shunt was dilated in three patients. In the two patients with both modified BT shunt and central shunt, the central shunt was completely occluded, and the modified BT shunt was dilated.

The interval between placing a modified shunt and an attempted angioplasty ranged from 27 days to 6.8 years. The size of the balloon used was generally equal to or slightly larger than the shunt diameter. When the balloon catheter selected could not pass the stenotic lesion, a balloon catheter of a smaller size or coronary balloon catheter was used, then progressively larger balloon catheters were employed. When PA stenosis was present, the same guidewire was positioned beyond the stenosis. Angioplasty for PA stenosis was performed concurrently, employing the same balloon catheter through the PTFE shunt. A pressure of 3 to 8 atm was applied to inflate the balloon. Then, larger sized balloon catheters were utilized to dilate the PA stenosis to the desired diameter. The size of the balloon selected for PA angioplasty was generally equal to or 1 to 2 mm larger than the PA diameter proximal to stenosis. When the desired size balloon catheter could not pass the PTFE shunt, a smaller size balloon catheter was used. All patients were monitored with pulse oxymeter and electrocardiogram during cardiac catheterization and angioplasty procedure. A postangioplasty angiogram was performed to evaluate the effectiveness of angioplasty. The narrowest diameter of the stenotic lesion of the modified BT shunt or subclavian arteries was measured on the repeated angiogram. Fifteen minutes after angioplasty, a second oxymetric study was performed. In the eight patients requiring supplemental oxygen before and during balloon angioplasty, repeat oxygen saturations were measured while receiving the same fractional inspired oxygen. We arbitrarily defined effective balloon dilation for obstructed modified shunts as an increase in the shunt diameter ≥20% or increase in systemic O2 saturation ≥3%. We also defined effective PA angioplasty as an increase in diameter of PA >50%. For patients with multiple stenoses in one vessel, an increase >50% in all stenotic lesions was regarded as effective angioplasty.

Statistical analysis. Data are expressed as mean ± standard deviation. A paired t test was used to compare the systemic O2 saturation data, diameter of narrowest dimension in a modified shunt and PA before and after angioplasty and the McGoon ratio and narrowest dimension in a shunt and PA after angioplasty and preoperative evaluation.

RESULTS

Balloon angioplasty for stenosed shunts and pulmonary arteries. Information about these 46 patients is listed in Table 1. A flow chart was also provided (Fig. 1). All patients...
tolerated the procedure. Of the seven patients with a central shunt, the stenosis occurred at the anastomotic sites or graft. Of the 39 patients with a modified BT shunt, stenosis was confined to a subclavian artery in 5, in the graft alone in 9, at the anastomotic sites in 6, in both graft and anastomotic site in 12 and in both the subclavian artery and graft in 7. The balloon-to-PTFE tube diameter ratio ranged from 0.8 to 1.5 (mean 1.13 ± 0.17). Postangioplasty subclavian arteriograms or aortograms confirmed that the stenoses in the PTFE shunts or subclavian arteries were partially or completely relieved in all 46 patients (Fig. 2). Excluding the seven patients with a central shunt in whom measuring the dimension of stenotic lesion was suboptimal, the mean diameter of the stenotic lesions in the grafts or subclavian arteries increased from 2.2 ± 0.7 mm to 3.2 ± 0.6 mm (p < 0.01) after balloon angioplasty in the 39 patients with modified BT shunts. Judging from the postangioplasty angiogram, pulmonary blood flow increased in most patients. Balloon angioplasty for the modified shunt was considered effective in 42 patients (91%) and ineffective in four patients. Dilation of PA stenosis or interruption was accomplished in 25 main branch PAs, but failed in three. The causes of technical failure in the three vessels were: inability to pass a floppy guidewire across the stenotic lesion in two vessels and failure to pass a balloon in one vessel. Excluding the patient with acquired interruption of right PA, the ratio of balloon size to narrowest diameter of PA stenosis ranged from 1.8 to 3.1 (2.3 ± 0.5). In the 25 vessels, the mean diameter of the stenotic PA segment increased from 2.8 ± 1.3 mm to 4.5 ± 1.9 mm (p < 0.01) after angioplasty. Dilation of PA stenosis was considered to be effective in 14 vessels where perfusion to PAs distal to the stenotic lesion was significantly increased after dilation (Fig. 3). Of the 11 vessels with ineffective PA angioplasty, four were long-segment central PA hypoplasia, two were shunt related stenosis, two were juxtaductal stenosis, two were multiple stenoses, and the remaining one was an acquired interruption of the right PA after a modified shunt in which there was significant stenosis requiring another shunt.

After the angioplasty, the mean oxygen saturation in the aorta increased from 74.4 ± 4.3% to 80.8 ± 3.6% in these 46 patients (p < 0.01). All except one had an increase in systemic O2 saturation ranging from 2% to 15%. The sole patient, who had a slight decrease in systemic O2 saturation

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<td>+</td>
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immediately after angioplasty, had a significant increase in systemic O₂ saturation measured with pulse oxymetry on the next day. The PGE₁ could be discontinued in the five of seven patients within seven days. The remaining two had required another shunt because of juxtaductal coarctation of a PA. One of the two patients who was intubated with ventilatory support could not be weaned from the respirator and died of pneumonia. Of the eight patients requiring O₂ inhalation, the oxygen could be discontinued after the procedure in six patients. A total of eight patients underwent a modified BT shunt soon after the procedure because of a severe stenosis or interruption in a PA. The remaining 37 patients were discharged with antiplatelet therapy (aspirin: 5 mg/kg/day).

Complications. No severe complications were encountered. No patient developed hemoptysis. Intimal tear of a PA was found in seven patients. A distal branch PA was occluded after angioplasty in one patient (Fig. 4). A transient drop in O₂ saturation was experienced in 38 patients who were treated by O₂ inhalation through a mask or hood and prompt withdrawal of the balloon catheter to the aorta. Six patients required heparin or streptokinase infusion because of transient loss of a femoral pulse.

Follow-up. During follow-up, one patient died of an accident, and one patient with asplenia syndrome died of an overwhelming infection. One patient was lost to follow-up. Twenty-nine patients underwent imaging studies for PA size and morphology 6 to 26 months (11.6 ± 5.4 months) after the initial intervention: four patients with a computerized tomography and 25 patients with an angiogram. The shunts that were dilated in previous balloon angioplasty were patent in all except one patient with complete occlusion. Two had recurrent stenosis of the shunt. In 23 patients with adequate images of BT shunts, mean dimension of the
stenotic lesion in the modified BT shunt was $3.1 \pm 1.1$ mm, compared with the mean diameter $3.3 \pm 0.7$ mm measured immediately after angioplasty; there was no significant difference ($p = 0.34$). Of the 18 PAs that were dilated in a previous angioplasty, the mean diameter of the narrowing segment increased from $5 \pm 1.8$ mm after angioplasty to $5.4 \pm 1.8$ mm on the follow-up angiogram ($p < 0.05$). No restenosis occurred in the PAs in which previous balloon angioplasty was effective. One patient underwent a concomitant PA balloon angioplasty with further increase in diameter of the stenotic lesion (Fig. 5). An aneurysm, which was not detected in previous angioplasty, was found at the anastomotic site of a shunt in a PA in one patient. Excluding the two patients with interruption of a PA, the McGoon ratio (sum of the diameter of left and right PA before first lobar branches/the diameter of the descending aorta at the level of diaphragm) increased from a mean of $1.49 \pm 0.2$ before angioplasty to $1.58 \pm 0.16$ ($p < 0.01$) at follow-up in the 27 patients. Of the 29 patients, 26 underwent an open-heart surgery: four for total cavopulmonary connection, six for bidirectional Glenn shunt, seven for Rastelli operation, one for ventricular septation, three for double switch, one for Kawashima procedure, one for right ventricular outflow tract patch, one for rerouting of pulmonary venous confluence to atrium and a shunt implantation and two for repair for tetralogy of Fallot. Of the 26 patients, a concurrent PA angioplasty was performed in eight patients. There were two mortalities. One patient underwent a modified BT shunt and PA augmentation because of a long segment central PA stenosis and inadequate PA index. Two patients await open-heart surgery. One patient (Patient 15) who survived bidirectional cavopulmonary shunt and PA reconstruction developed severe atrioventricular valve regurgitation and impaired ventricular function. She underwent a cardiac transplantation with success. Excluding those who underwent a surgery, there were nine patients available for follow-up. After a mean follow-up period of $7.8 \pm 6.3$ months; the mean $O_2$ saturation measured with pulse oximeter was $79.2 \pm 2.6\%$ in these nine patients.
DISCUSSION

Dilation of PTFE shunts as an alternative to a second shunt. The percutaneous balloon dilation technique has been widely employed to treat congenital valvular and vascular stenosis with satisfactory results (18). This technique has been successfully applied in patients with stenosed standard BT shunts and can be an alternative procedure to a second shunt (10–14). Therefore, a standard BT shunt is recommended as the first choice of systemic to PA shunt because it is uniquely dilatable (14). In this study, dilation for stenosed modified shunts, which was accomplished in 46 of 49 patients, was effective in 42 patients (91%). A modified BT shunt or a modified central shunt is advocated as an initial palliation in complex cyanotic heart disease because dilation can be performed in most patients with stenosis of the modified shunts. An effective dilation for a stenosed PTFE shunt may eliminate the need for a second shunt, particularly for patients with complex heart disease in whom further PA distortion may occur after a shunt (15–17,19). Although the bidirectional cavopulmonary shunt and a concurrent PA angioplasty have been recommended for infants who are Fontan-type surgery candidates.

Figure 3. (A) Significant stenosis related to a ductus at the right pulmonary artery is illustrated. (B) After balloon angioplasty, pulmonary artery stenosis was relieved.

Figure 4. (A and B) A selective angiogram illustrating multiple stenoses, (arrowheads) in the modified Blalock-Taussig shunt in a patient who underwent unifocalization of the pulmonary arteries. There were stenoses in distal pulmonary arteries. (C and D) After angioplasty, the stenoses in the shunt were relieved with increased pulmonary blood flow. There was occlusion of a left distal pulmonary artery (arrow).

Figure 5. (a) Significant stenosis (arrowhead) at the left pulmonary artery related to a modified Blalock-Taussig shunt is shown. Balloon dilation was performed in this patient. (b) A repeated pulmonary arteriogram 18 months after balloon angioplasty showing mild stenosis (arrowhead) at the left pulmonary artery. (c) After the repeated angioplasty, the stenosis at the left pulmonary artery was completely relieved.
Simultaneous dilation of pulmonary artery stenosis. Stenosis of the modified PTFE shunt can occur in the subclavian artery adjacent to the anastomotic site, the graft and anastomotic sites. The stenosis at the anastomotic site may result from scar formation, while the stenosis in the PTFE tube may be due either to fibrous neointimal peel or to organized thrombosis (17). The mechanism of the action of balloon angioplasty in dilation of the PTFE tube may involve dissection and disruption of the fibrous neointimal peel or thrombi. Employing a balloon slightly larger than the graft diameter appears to be beneficial and safe although an aneurysm at the anastomotic site of a PTFE tube and the PA was seen in one patient. This could be the result of a tear at the anastomotic site. Dislodgment of intimal lining causing thrombosis of a distal branch PA could be a problem after dilation of the modified shunt. In the patient who developed obstruction of a distal branch of a PA, a right ventricular outflow tract reconstruction was performed without any major complication. In this study, the interval between a shunt placement and balloon angioplasty was no less than three weeks because immature scar tissue may not tolerate dilation with high pressure and an oversized balloon, which was selected for dilating both the shunt and PA (21). For balloon angioplasty for early postoperative shunt failure, a balloon with a diameter smaller than the shunt has been recommended (16). Advancing a catheter to a modified BT shunt at the left subclavian artery via a retrograde aortic route in a patient with a right aortic arch can be difficult. An anterograde route from the femoral vein to the aorta is a possible alternative approach in such patients with double outlet right ventricle or tetralogy of Fallot (14). A modified central shunt can be entered with a right coronary catheter without much difficulty, but successful balloon angioplasty for a modified central shunt has rarely been reported in literature. There was failure in balloon angioplasty for stenosed PTFE shunts, which occurred in early experience here. Since early 1995, after the procedure has become more familiar, almost every case has been successful.

Technical aspects and complications of dilating stenosed modified shunts. Stenosis of the modified PTFE shunt can occur in the subclavian artery adjacent to the anastomotic site, the graft and anastomotic sites. The stenosis at the anastomotic site may result from scar formation, while the stenosis in the PTFE tube may be due either to fibrous neointimal peel or to organized thrombosis (17). The mechanism of the action of balloon angioplasty in dilation of the PTFE tube may involve dissection and disruption of the fibrous neointimal peel or thrombi. Employing a balloon slightly larger than the graft diameter appears to be beneficial and safe although an aneurysm at the anastomotic site of a PTFE tube and the PA was seen in one patient. This could be the result of a tear at the anastomotic site. Dislodgment of intimal lining causing thrombosis of a distal branch PA could be a problem after dilation of the modified shunt. In the patient who developed obstruction of a distal branch of a PA, a right ventricular outflow tract reconstruction was performed without any major complication. In this study, the interval between a shunt placement and balloon angioplasty was no less than three weeks because immature scar tissue may not tolerate dilation with high pressure and an oversized balloon, which was selected for dilating both the shunt and PA (21). For balloon angioplasty for early postoperative shunt failure, a balloon with a diameter smaller than the shunt has been recommended (16). Advancing a catheter to a modified BT shunt at the left subclavian artery via a retrograde aortic route in a patient with a right aortic arch can be difficult. An anterograde route from the femoral vein to the aorta is a possible alternative approach in such patients with double outlet right ventricle or tetralogy of Fallot (14). A modified central shunt can be entered with a right coronary catheter without much difficulty, but successful balloon angioplasty for a modified central shunt has rarely been reported in literature. There was failure in balloon angioplasty for stenosed PTFE shunts, which occurred in early experience here. Since early 1995, after the procedure has become more familiar, almost every case has been successful.

Simultaneous dilation of pulmonary artery stenosis. Pulmonary artery distortion after a systemic-PA shunt is common (7,8,19). Pulmonary artery stenosis related to duc tus is also frequent in complex cyanotic heart disease (22–24). In the presence of PA stenosis, growth of the PA distal to stenosis can be hampered. A successful angioplasty may provide relief of PA stenosis or improve perfusion to the underperfused lung and growth of distal PA, greatly increasing the chances for later Fontan-type or Rastelli surgery (21). Surgical angioplasty for PA stenosis related to a ductus or shunt may be a problem and, for this reason, balloon dilation of PA stenosis before definitive surgery would be an alternative to surgical reconstruction of PAs (22–25). Several complications from balloon angioplasty for PA have been reported in literature including aneurysm, hemoptysis, heart block and death (21,26). Tearing in intima and media, which was not infrequent after balloon angioplasty, was a mechanism and also a predictor for successful PA angioplasty (26,27). The success rate of angioplasty for branch PA stenosis was reported to be 58% (21). In two reports, surgery-related PA stenosis was considered to be amenable to balloon dilation (27,28). In a report by Gentles et al. (26), using a high-pressure balloon in dilation of surgery-related lesions was nearly always successful. In this study, balloon angioplasty for PA stenosis was performed through a modified shunt. Branch PA stenosis was effectively dilated in 14 of 28 attempts (50%). The balloon size selected in this study was generally smaller than those recommended in literature (21,26). This was attributed to the relatively smaller caliber of PTFE shunt allowing for passage of smaller size balloons. Balloon angioplasty for neonates or young infants with ductus-related PA stenosis may not provide long-term relief of stenosis, because closure and fibrosis of ductal tissue may lead to restenosis (24). Restenosis of PA to pre-dilation size occurred in 10% to 16% of patients (21,26). In this series, no restenosis was detected in the PAs, which were effectively dilated.

Study limitations. There were several limitations in this study. This is a retrospective study. The definitions of success in angioplasty for stenosed shunts and PA stenosis are quite arbitrary. We used an increase in shunt diameter ≥20% or systemic O2 saturation ≥3% as criteria for effective dilation for shunts. However, the increase in systemic O2 saturation after the procedure cannot be attributed to the effect of dilation for the shunts alone. A concurrent angioplasty for PA stenosis may also contribute to the relief of hypoxemia. An increase of PA diameter >50% may not be a perfect criterion for effective PA angioplasty. In many patients with effective angioplasty, there are varying degrees of PA stenosis left that may compromise later Fontan circulation. Eight patients in the current series required a patch angioplasty for PAs at the time of an open-heart surgery. Understanding the long-term effects of balloon angioplasty for branch PA stenosis requires further studies. We observe that many of the patients may need an endovascular stent placement in the future (29).

Conclusions. When a second shunt is under consideration because of obstruction of a PTFE shunt, balloon angioplasty to dilate the stenotic sites may be an alternative to another shunt. Balloon dilation for a PA stenosis, either ductus or shunt-related, can be performed concurrently. This is particularly true for patients who are candidates for Fontan-type surgery, because a second shunt may incur risk and further distort PAs.

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