

## Original Article

# Refinements in the implantation of pulmonary arterial stents: impact on morbidity and mortality of the procedure over the last two decades

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**Abstract** *Introduction:* There is limited data on medium to long-term outcome, and the morbidity and mortality associated with the implantation, of pulmonary arterial stents. *Purpose:* To assess changes in morbidity and mortality over the last two decades. *Methods:* Retrospective analysis of all patients stented between September, 1989 and July, 2001. *Results:* We implanted 664 Palmaz stents in 338 patients. The overall number included 229 patients who had undergone repair of tetralogy of Fallot, in whom 468 stents were implanted, 61 patients with congenital stenosis of the branches of the pulmonary trunk, in whom we placed 115 stents, 16 patients after an arterial switch operation who had 38 stents, and 32 patients after the Fontan operation who had 43 stents implanted. The mean age was 12.2 years, and the mean weight was 38 kg. The mean systolic pressure gradient decreased from 41 to 8.7 mmHg, the mean diameter of the stented vessel increased from 5.4 to 11.2 mm, and the ratio of right ventricular to femoral arterial pressure decreased from 0.66 to 0.45, each of these being significant at the level of p being less than 0.01. At a mean follow-up of 5.6 years, the mean gradient was 20 mmHg, the mean ratio of pressure between right ventricle and femoral artery was 0.5, and mean luminal diameter was 9.3 mm. Complications included migration of the stent in 8 patients, and pulmonary edema, hemoptysis and death in 5 patients each. There has been no mortality or morbidity since July of 1997. Technical changes include conservative serial dilations in congenital pulmonary arterial stenosis, avoidance of over-dilation, and simultaneous implantation of stents in the right and left pulmonary arteries in those with systemic pulmonary arterial pressure. Technological advances included shorter stents, improved balloon profiles, and central inflation of the stents. *Conclusions:* Modification of stenting practices, and increased experience of the operators over the last two decades, has virtually abolished any morbidity or mortality associated with the implantation of stents for congenital or postoperative pulmonary arterial stenoses.

Keywords: Pulmonary arteries; tetralogy of Fallot; stent; congenital cardiac disease

## Introduction

Immense strides have been made in the development of and application of endovascular stents in congenital cardiac disease since their first successful application

to maintain the patency of vessels by Dotter in 1969.<sup>1</sup> Their application to the population of children with congenital cardiac malformations was not until the late 1980s, when initial trials using balloon expandable stents primarily focused on patients with congenital and acquired pulmonary arterial stenosis.<sup>2–6</sup> This has been rapidly followed over the last twelve years by their application in treating coarctation of the aorta,<sup>7–8</sup> central and systemic venous obstructions,<sup>9</sup> postoperative conditions, including obstructions of cavo-pulmonary communications, conduits

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and homografts,<sup>10</sup> and in more recent years their use by some investigators to preserve patency of the arterial duct.<sup>11</sup>

Although the early to medium term results of stents placed in the pulmonary arterial circulation are promising, there is limited data regarding their medium to long-term outcome.<sup>12</sup> Over the last two decades, the ubiquitous application of endovascular stents in the treatment of congenital cardiac defects has brought about specific refinements in the techniques used by the operators, and changes in stenting practice, which have produced impressive changes in the morbidity and mortality associated with such procedures. These advances are well demonstrated by the experience reviewed in this study.

## Methods

We retrospectively reviewed all patients at our institution who underwent placement, using specific protocols, of balloon expandable Palmaz stents (Palmaz Johnson & Johnson, Piscataway, New Jersey) between September 1989 and July 2001. All demographics were studied, including age, weight, sex, diagnosis, past surgical history, including interval from the time of initial implantation of stents to the time of most recent follow-up. Patients were classified into one of four groups according to their anatomy. The data from cardiac catheterization at the time of initial implantation of stents, and on follow-up, were examined to determine the initial systolic pressure gradient, the luminal diameter, the number and dimension of stents initially implanted, the reduction in pressure gradient, in appropriate cases expressed as a ratio of the systolic right ventricular and femoral arterial pressures, and the increase in diameter of the stented vessels. Medical records were reviewed to determine recent follow-up, and to document any complications of stenting, including migration or compression of the stent. We also analyzed mortality in those stented to determine cumulative survival.

## Statistics

Comparison of the systolic pressure gradient, minimal vessel diameter, and change in the ratio of systolic right ventricle to femoral arterial pressure before and after implantation of stents, were made using paired Student's t-test. Statistical significance was defined as a p value of less than 0.05.

## Definitions

*Restenosis* was defined as a reduction in the luminal diameter of the stent less than the adjacent nominal diameter of the stented vessel, and/or a development or increase in pressure gradient across the stent.

*Neointimal proliferation* was defined as a lining between the stent and the lumen seen angiographically. Mild or physiological intimal hyperplasia was defined as less than 1 mm on either side of the stented vessel, moderate as a thickening of 1–1.5 mm, and severe when the lining was thicker than 1.5 mm.

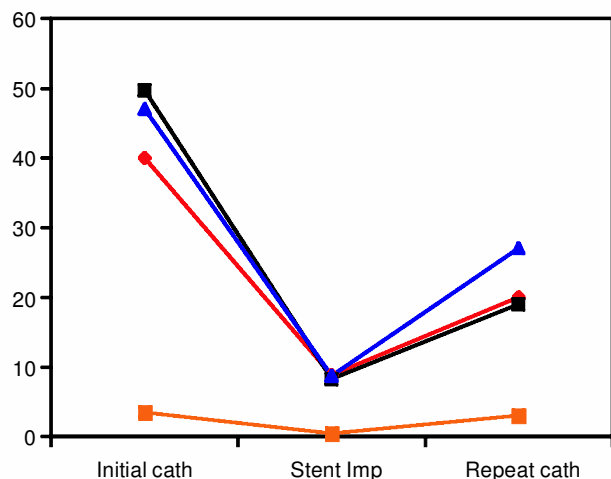
## Results

### *Demographics*

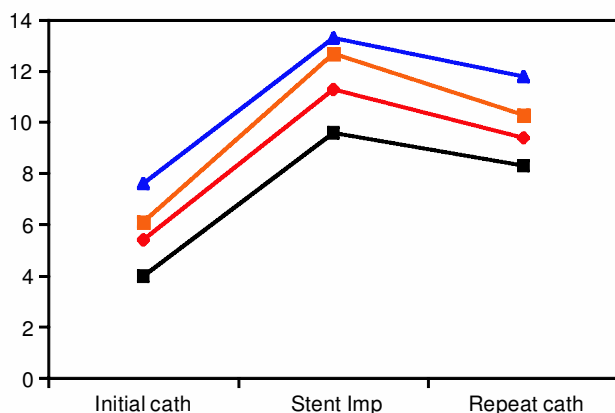
A total of 664 balloon expandable stents (Palmaz Johnson & Johnson, Piscataway, New Jersey) were placed in the pulmonary arteries of 338 patients during the period of study. Of those, 468 stents were implanted in 229 patients following repair of tetralogy of Fallot, 115 stents were placed in 61 patients with congenital stenosis of the right and left pulmonary arteries, 38 stents were placed in 16 patients following an arterial switch operation, and 43 stents in 32 patients following a Fontan operation. The mean age at implantation of stents was 12.2 years, with a range from 0.4 to 48 years. The mean weight at time of implantation of stents was 38 kg, with a range from 5 to 96 kg. The mean duration from initial implantation of stents to clinical follow-up was 5.6 years, with a range from 0.2 to 10.2 years. Cardiac catheterization had been repeated in 220 patients by January 2001. These included 147 patients following repair of tetralogy of Fallot, 43 patients with congenital stenosis of the right or left pulmonary arteries, 8 who had undergone an arterial switch, and 22 patients with the Fontan circulation. In the first 6 years of our experience, the mean number of stents placed per patient was 1.6 per patient for those with tetralogy, 1.5 per patient with congenital stenosis of the right or left pulmonary arteries, 1.7 per patient after an arterial switch operation, and 1.3 for patients undergoing a Fontan operation. In the second 6 years, the mean number of stents placed was 2.4 for those with tetralogy, 2.1 for the ones with pulmonary arterial stenosis, 2.3 for the patients undergoing an arterial switch, and 1.3 for those having a Fontan procedure. An increased number of stents were implanted later in our experience, when we had realized the importance of simultaneous implantation of stents in adjacent branches of the pulmonary trunk, and also appreciated that implanting several shorter overlapping stents would better assume the curvilinear angulation of the branches of the pulmonary trunk, producing less neointimal proliferation or restenosis. The rate of restenosis was 2%, and neointimal proliferation was 4%.<sup>13</sup>

### *Hemodynamic outcomes*

In accordance with previously published studies, the mean peak systolic gradient change, the mean ratio of



**Figure 1.** Change in mean pressure gradient (expressed as mmHg) after initial stent placement. Y-axis represents gradient.  $\blacklozenge$ : TOF;  $\blacksquare$ : CBPS;  $\blacktriangle$ : ASO;  $\blacksquare$ : Fontan.

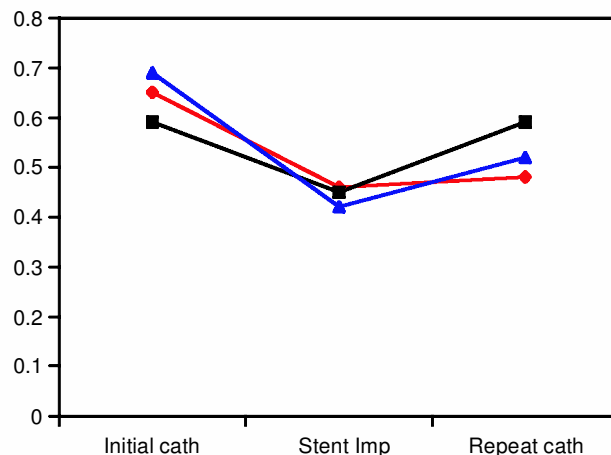


**Figure 2.** Change in the mean luminal diameter expressed as millimeters after initial stent placement and on follow-up catheterization. Y-axis represents luminal diameter.  $\blacktriangle$ : TOF;  $\blacksquare$ : CBPS;  $\blacklozenge$ : ASO;  $\blacksquare$ : Fontan.

right ventricular to femoral arterial pressure, and the mean luminal change in diameter of the vessel after implantation of stents, were recorded for each group.

#### Hemodynamics and changes in luminal diameter

Changes in pressure gradient, luminal diameter, and the ratio of right ventricle to femoral arterial pressure are expressed in Figures 1–3. At initial catheterization, the mean peak systolic gradient decreased from 40 to 8.8 mmHg, 49.7 to 8.3 mmHg, 47 to 8.4 mmHg and from 3.5 mmHg to 0.5 mmHg for those with tetralogy, congenital stenosis of the right or left pulmonary arteries, after an arterial switch, and after a Fontan procedure, respectively ( $p < 0.01$ ). At the most recent catheterization, these values had increased to 20, 19, 27, and 3 mmHg, respectively.



**Figure 3.** Changes in the ratio of the right ventricle to femoral arterial pressure after implantation of initial stent and on follow-up catheterization.  $\blacklozenge$ : TOF;  $\blacksquare$ : CBPS;  $\blacktriangle$ : ASO.

The mean ratio of pressure between the right ventricle and the femoral arteries at the initial cardiac catheterization decreased from 0.65 to 0.46, 0.59 to 0.45 and from 0.69 to 0.42 for the groups, respectively ( $p < 0.01$ ). On follow-up, the values increased to 0.48, 0.59, and 0.52 respectively. The mean luminal diameter of the pulmonary artery increased overall from 5.6 to 11.4 mm after placement of the stent ( $p < 0.01$ ). In the majority of cases, gradients were generated because the vessel wall had undergone growth adjacent to the static stent despite the absence of restenosis within the stent. Such stents were successfully redilated to a luminal diameter equal to that of the adjacent vessel wall in the majority of patients without any complications.<sup>13</sup>

#### Complications: morbidity

##### Pulmonary edema

Between September 1989 and December 1997, there were 5 cases of significant pulmonary edema, defined as a combination of symptoms with new onset, accompanied by evidence of pulmonary edema on the chest radiograph. All cases resulted from implantation of the stent in distal isolated pulmonary arterial segments in patients with systemic or suprasystemic right ventricular pressures. One patient with familial non-Williams congenital stenosis, with systemic right ventricular pressure, underwent placement of two stents to the left lower lobe segment with flooding of the segment, and died within 48 hours. Of note, she had a brother with congenital stenosis of a pulmonary artery who died from right heart failure at 8 years of age. One patient required temporary intubation and mechanical ventilation, and was extubated within 24 hours and discharged home within

48 hours of catheterization. No cases had occurred since December, 1997.

### *Hemoptysis*

Between 1990 and 1995, there were 5 cases of significant hemoptysis following implantation of a stent. Three patients stented after repair of tetralogy of Fallot developed hemoptysis following placement of stents secondary to small tears in peripheral vessels related to manipulation of superstiff wires. One patient with congenital stenosis of a pulmonary artery developed significant hemoptysis and required subsequent lobectomy to control bleeding. Despite this, the patient died one week after implantation of the stent. A second patient with congenital pulmonary arterial stenosis had moderate hemoptysis following implantation of a stent in the right pulmonary artery which self-resolved. The other 3 patients transiently experienced mild hemoptysis, which resolved within 24 hours. No cases have occurred since January 1995.

### *Migration, compression, and thrombosis of stents*

Between September 1989 and December 1997, there were 8 cases of migration. Two of these stents embolized proximally, one to the right ventricle and the second one to the pulmonary trunk, and were removed surgically prior to 1994. Six other stents became unstable, migrated distally, and were "captured" and balloon-expanded in a site other than that originally intended with no harm to the patient. On follow-up there were no cases of subsequent migration from the site of initial implantation. Three patients with cavo-pulmonary communications developed thrombosis within the stents, two of whom had ipsilateral pulmonary venous stenosis. The other patient had a right atrial thrombus, which extended into the stent. In the first 3 years of stenting, 3 patients developed retroperitoneal hemorrhages, presumably secondary to the size of sheaths, catheters, and balloons used in the iliac vessels. Since 1995, there have been no cases of thrombosis or retroperitoneal hemorrhage. All patients are treated with aspirin for the first 6 months after implantation of a stent. There were 3 cases of deformation of right pulmonary arterial stents secondary to aortic pulsation, each of which were successfully treated without complication by placement of an additional Palmaz 308 stent within the compressed stent.

### **Complications: mortality**

#### *Catheterization-related deaths*

There were 5 deaths, all occurring prior to 1998. One patient with stenosis of the pulmonary arteries

developed massive hemoptysis following bilateral implants, and after development of a broncho-pulmonary fistula required lobectomy but died one week after surgery. One patient after repair of tetralogy of Fallot with suprasystemic right ventricular pressure died secondary to a tear in the pulmonary trunk 5 weeks after implantation of stents. Further surgical intervention had been previously refused in this patient. A third patient following repair of a common arterial trunk, who had severe bilateral stenosis of the pulmonary arteries and systemic right ventricular pressure, developed severe bradycardia and hypotension after placement of the stent in the right pulmonary artery and failed to respond to resuscitative measures. Postmortem coincidentally demonstrated co-existent myocarditis. The fourth patient described above died following development of severe isolated segmental pulmonary edema. The final patient, after a Fontan operation, underwent placement of a stent in the left pulmonary artery. On angiography, significant thrombus was seen to have accumulated in the lateral tunnel. He died from massive pulmonary embolism within 48 hours of cardiac catheterization.

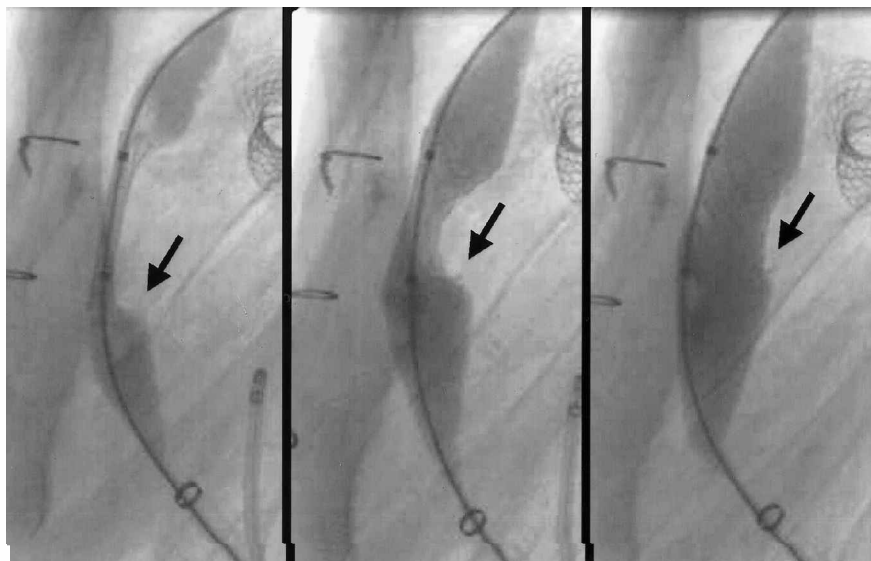
### **Long-term survival**

Cumulative survival was 0.99 at 10 years for those with tetralogy group, 0.96 for the ones with congenital stenosis of the pulmonary arteries, 0.93 for those having had a Fontan procedure, and 1.0 for those having had an arterial switch procedure. There were 3 late deaths not related to catheterization. The first patient died from presumed ventricular tachyarrhythmia after repair of tetralogy 2 years following placement of stents in the right pulmonary artery and the pulmonary trunk. The second patient was referred from an outside institution with a right atrial-pulmonary arterial anastomosis and severe ventricular dysfunction. Stents were implanted in the right pulmonary artery. His ventricular dysfunction deteriorated further and he died soon after discharge home. The third patient had undergone a Fontan procedure and developed plastic bronchitis with elevated central venous pressure requiring placement of a stent in the right pulmonary artery, but died from refractory production of casts 8 weeks later.<sup>14</sup>

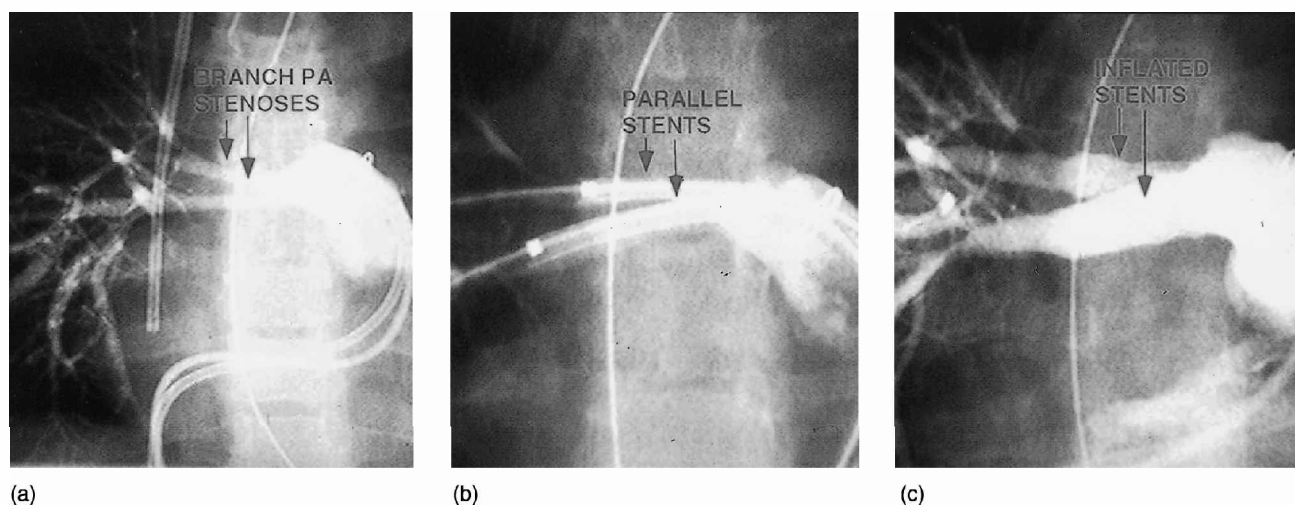
### **Modification of stenting practices**

The majority of catheterization related complications arose early in our experience. Over the last two decades, several modifications in stenting technique, in combination with technological advances, have heralded a dramatic reduction in these complications. The potential for hemoptysis has been minimized by avoiding overdilation of the stented vessel





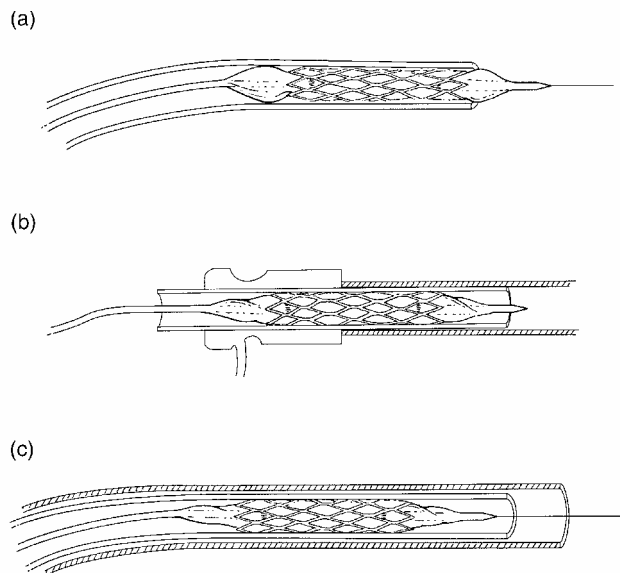
**Figure 4.**  
Inflation of a previously used “poor-profile balloon” demonstrating protrusion of distal stent struts into the vessel wall (arrow).



**Figure 5.**  
Simultaneous implantation of stents in the pulmonary arteries following tetralogy repair: (a) Severe stenoses of the right pulmonary arteries; (b) parallel stents prior to implantation; (c) following parallel implantation.

greater than the adjacent nominal vessel diameter in patients with Williams syndrome or elastin arteriopathy. From a technical standpoint, inflating the center of the stent prior to the end prevents protrusion of the stent strut into the wall of the vessel and hence minimizes risk of vessel damage (Fig. 4). Pulmonary edema was minimized by simultaneous implantation of stents in adjacent pulmonary arteries (Fig. 5), and by abandoning isolated dilation of stents in distal pulmonary arteries in patients with systemic or suprasystemic right ventricular pressures. Migration of stents has been minimized by optimizing the initial position of the stent through a series of steps, including optimizing and maintaining distal position of a stiff wire prior to placement of the long sheath, and by confirming the central position

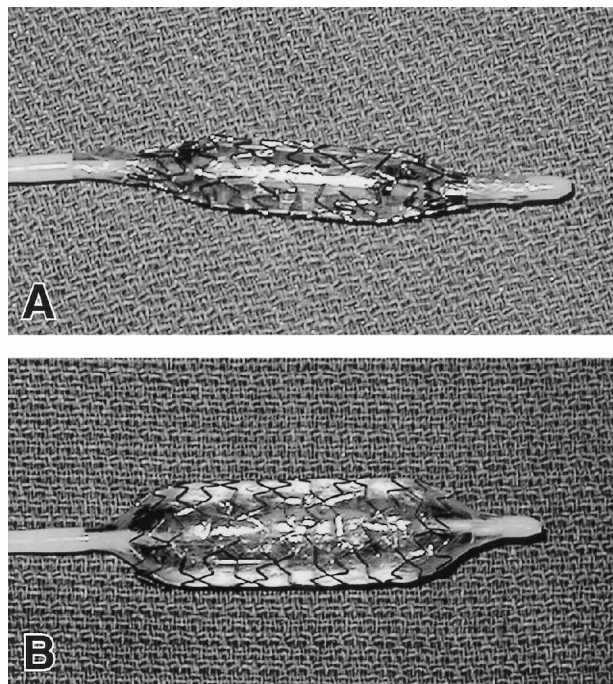
of the stent on the balloon using fluoroscopy prior to introduction into the sheath. The position of the stent on the balloon should be rechecked once placed within the sheath. A front-loading technique may be used where the stent is placed over the balloon and into a long sheath prior to introduction into the body. The distal end of the balloon acts as the dilator for the long sheath (Fig. 6a). After the long wire is in place, the sheath with balloon and stent are positioned over the area of stenosis. One potential problem is the lack of a transition between the balloon tip and the sheath. Hence, insertion into the femoral vein may be difficult. The front-loading modification devised by Ing et al. may also be used where the stent and balloon are loaded into a modified smaller sheath (Fig. 6b).<sup>15</sup> The tip of the dilator that



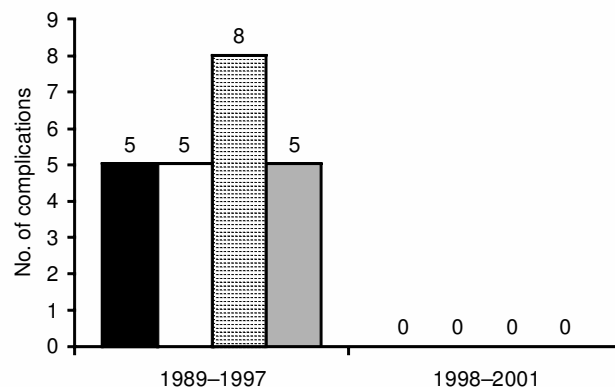
**Figure 6.** Illustrative drawing demonstrating different methods of delivering balloon and stent. (a) Standard technique; (b) Ing-modification; (c) sheath-within-sheath.

accompanies the sheath is cut off and wedged onto the balloon tip in order to provide a smooth transition between balloon and sheath. The smaller long sheath with balloon and stent are then advanced into the femoral vessel to the site of stenosis without risk of the stent milking off the balloon during advancement. A “sheath-within-sheath” technique may also be used to overcome acute arterial corners (Fig. 6c). This involves front-loading the stent on the balloon into a smaller long sheath outside the body. The smaller sheath, with the balloon and stent already front loaded, is introduced into the second larger but shorter sheath inserted into the femoral vessel. This avoids the stent “milking” off the balloon while traversing tight curves, and prevents the distal end of the balloon impinging on intra-cardiac structures. After the stent is introduced into the sheath, a small amount of positive pressure is applied to hold the stent in place (Fig. 6a). After implantation of the stent, to re-introduce the long sheath, the balloon is inflated slightly while the sheath is advanced over the wire to center the sheath in the middle. This minimizes the potential for displacement of the stent.

Improved technological advances in balloons, optimizing placement, have included a “short-shoulders” balloon profile, and a usable balloon length equal to or shorter than the stent. Greater use of shorter stents confers the benefit of significantly less regression into the pulmonary trunk. Balloon in balloon inflation, using the BIB balloon (Numed Inc., Nicholville, New York) allows inflation of the central

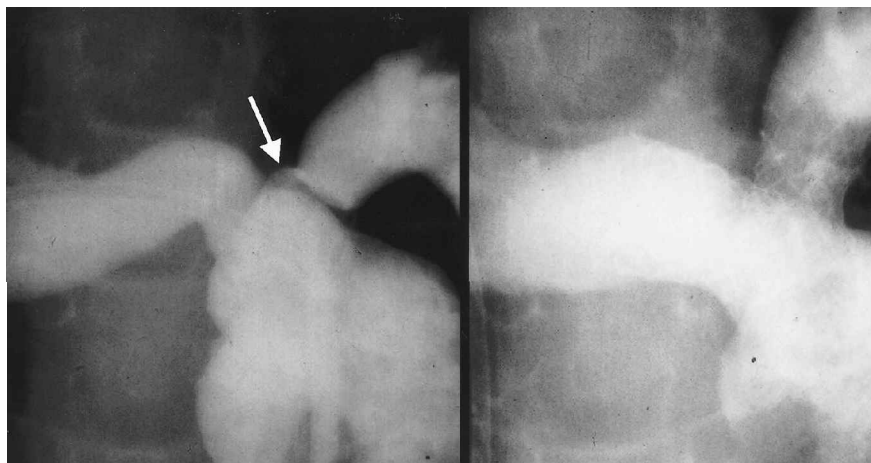


**Figure 7.** Use of the inner BIB balloon to first inflate the central part of the stent (A) prior to the stent ends (B), thus preventing distal protrusion of struts.



**Figure 8.** Comparison of complications related to stenting between September 1989 – December 1997, and January 1998–2001. ■: Pulmonary edema; □: hemoptysis; ▨: stent migration; ▩: death.

part of the stent prior to its ends, avoiding penetration of the distal stent struts into the vessel wall (Fig. 7). The introduction of these practices resulted in no further complications, including migration, pulmonary edema, hemoptysis, or deaths since January, 1998 (Fig. 8). These modifications were implemented by this time, with the exception of the BIB balloon, which was first available to us in 2000.



**Figure 9.**  
*Rehabilitation of a severely stenotic left pulmonary artery following placement of a stent after repair of tetralogy of Fallot.*

## Discussion

The rehabilitation of diminutive and stenotic pulmonary arterial vessels has proven one of the greatest challenges to the pediatric cardiologist over the last decade (Fig. 9). Developments in implanting endovascular stents in the treatment of congenital cardiac defects, both operated and native, has been impressive since the introduction of implantation of stents by Mullins et al.,<sup>2</sup> just over a decade ago. This is true not only for the treatment of arterial stenoses within the pulmonary tree,<sup>3,4</sup> but also for obstructed homografts or conduits,<sup>10</sup> coarctation of the aorta,<sup>7,8</sup> occluded systemic veins and baffles,<sup>9</sup> and in more recent years, in attempts to preserve ductal function where deemed appropriate.<sup>11</sup> This report documents our experience over the first decade of the largest reported number of balloon expandable stents placed in the pulmonary arterial circulation of a heterogeneous population at a single center.

Although the hemodynamic benefits from implantation of stents are unequivocal over balloon angioplasty, with significantly lower rates of restenosis, the long-term natural history after placement of pulmonary arterial stents is not fully known.<sup>16–18</sup> In our study, the follow-up in the medium term was encouraging, with minimal mortalities at a mean follow-up of 5.6 years after initial implantation. The incidence of restenosis, at 2%, and non-physiologic neointimal proliferation, also at 2%, was extremely low.<sup>13</sup> This is further encouraging when one bears in mind that several patients were not deemed suitable surgical candidates because of diffuse severely stenotic pulmonary arteries and systemic or supra-systemic right ventricular pressure. The safety and efficacy of redilating endovascular stents, most commonly for somatic growth, has also been previously well reported.<sup>19,20</sup>

As with all new technologies and medical practices, there are initial learning curves which result in some degree of complication or adverse outcome. Perhaps the most pertinent learning point from our data is the importance of rationalizing reasons for adverse outcome in the interventional catheterization setting. Perhaps even more important to realizing sources of error in stenting technique is the stringent improvisation of refinements in technique to avoid the re-occurrence of such complications. Certain principles learned at an early stage in our experience included the importance of simultaneously stenting and dilating several branches in patients with moderate to severe right heart hypertension to avoid flooding a single lung segment and collapsing other adjacent vessels.<sup>4,21</sup> Likewise, avoidance of overdilation of stenotic vessels in patients with elastin-arteriopathic stenosis reduced the incidence of tears and hemoptysis. Patients in this latter group often prove problematic, since the vessel wall does not react normally to implantation of stents, and may contract the stent down resulting in early restenosis.<sup>21,22</sup>

Specific refinements in technique in addition to increased operator experience have also minimized potential complications. Confirmation of the central position of the stent on the balloon using fluoroscopy, protection of the sheath and balloon within the short sheath hub prior to introduction into the long sheath, and application of a small amount of positive pressure to hold the stent in place helping prevent dislodgement from the balloon while gaining access to the area of stenosis, are particularly important in ensuring successful, and equally important “intact”, arrival of the stent. Simultaneous advancement of the sheath and stent while traversing acute arterial corners also serves to minimize the risk of dislodgement from the balloon or distortion. It must



be stressed, however, that despite these modifications, including the front-loading technique or the “sheath-within-sheath” technique, there always remains a risk of the stent milking off the balloon while traversing acute arterial curves. Even inflating the balloon with the stent in place may not be sufficient to prevent it milking off the balloon during such manipulation. After implanting the stent, during re-introduction of the long sheath, the balloon is inflated slightly while the sheath is advanced over the wire to center the sheath in the middle and again avoid dislodgement.<sup>23</sup>

Certain manufacturing advances have also aided stenting practices. Technological advances in particular have optimized this technique. The BIB balloon (Numed, Inc. Nicholville, New York) has the benefit of a “short-shoulders” profile. It has a usable balloon length equal to or shorter than the stent. Inflating the inner BIB balloon first allows inflation of the central part of the stent prior to its ends, hence optimizing positioning and preventing penetration of distal struts into the adjacent vessel wall. In earlier cases, we noted with longer profiled balloons there was a tendency for the ends of the balloon to inflate first, which caused the strut ends of the stent to project into the vessel wall (Fig. 7). This has the potential to cause tears and, in addition, may irritate the vessel wall sufficiently to act as a template for the development of restenosis.

There are several limitations worthy of mention. This study was retrospective in nature, which has well-recognised inherent limitations. It has also only addressed the outcome of balloon expandable stents in one center. Their outcome may not be representative of that of the general interventional catheterization community. Thirdly, we have only reported our experience of balloon expandable Palmaz stents. Further studies are necessary to compare their efficacy and complication rates to other designs, such as the ITI stents (Intratherapeutics, St. Paul, Minnesota). The techniques and detail to consistent placement is personal to this institution, and may not be echoed by other units. Finally the impact of surgical and medical management in our patients may have had significant impact on morbidity and mortality, and it is impossible to gauge the efficacy of implantation of stenting in isolation given such adjunctive therapies.

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