Implantation and Intermediate-Term Follow-up of Stents in Congenital Heart Disease

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Background. Balloon-expandable stents (Johnson and Johnson Interventional Systems) have been in use for congenital heart disease since late 1989. They have made possible treatment in previously untreatable branch pulmonary artery stenoses and systemic venous stenosis. The purpose of this report is to detail the results and intermediate-term follow-up of stents used for treatment of congenital heart disease.

Methods and Results. Eighty-five patients underwent placement of 121 stents in Houston and Boston. Fifty-eight patients had stents put in pulmonary arteries, nine had stents in conduits or outflow tracts, and 21 had stents in venous stenoses or narrowed Fontan anastomoses. (Three patients had stents in two locations.) These stent procedures resulted in gradient reduction from 55.2±33.3 to 14.2±13.5 mm Hg in pulmonary arteries, from 41.4±26.0 to 20.7±17.0 mm Hg in conduits or outflow tracts, and from 9.8±6.9 to 2.4±3.1 mm Hg in venous stenoses or Fontan anastomoses. Diameter of narrowings increased from 4.6±2.3 to 11.3±3.2 mm in the pulmonary artery, from 8.8±3.6 to 12.7±2.6 in conduits, and from 3.8±2.9 to 11.3±2.8 in venous stenoses. Follow-up has shown stent fracture in one patient, restenosis in one, and sudden death in one. Catheterization has been done in 38 patients an average of 8.6 months after stent implantation. Compared with immediately postimplant data, there was no significant change in luminal diameter or pressure gradient. Redilation was performed in 14 patients (17 stents) 1 week to 24 months after implantation (mean, 10.2 months), with a small but significant increase in stenosis diameter.

Conclusions. We conclude that stent treatment of vascular stenoses in congenital heart disease retains efficacy at medium-term follow-up and offers a much-improved outlook for patients with these lesions. (Circulation 1993;88:605-614)

KEY WORDS • pulmonary artery • dilation • veins • stenosis • angioplasty

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tenoses of branch pulmonary arteries and narrowings of venous channels have been difficult to treat surgically. One recently developed technique to relieve these stenoses has been endovascular stent implantation. Initial research in balloon-expandable stents in congenital heart disease suggested feasibility of implantation and showed gratifying immediate results. Compared with balloon dilation alone of pulmonary arterial narrowings, dilation with stent placement gave better results with regard to diameter increase and pressure gradient reduction. The purposes of this article are to report the results of stent placement of patients with narrowings due to congenital heart disease, to give follow-up data in these patients, and to discuss the evolution and invention of techniques used for stent implantation.

Methods

Eighty-five patients with congenital heart defects underwent cardiac catheterization and placement of a total of 121 endovascular stents between September 1989 and April 1992. In a previous report, implantation and short-term follow-up of 30 patients were outlined. Twenty-eight of these are discussed; excluded are the two unusual uses in the descending aorta and pulmonary veins. Exclusion of these patients changed the age and weight ranges slightly; inclusion of the 28 permitted description of the longest-available follow-up and recatheterization data. The procedures were performed at Texas Children’s Hospital in Houston and Children’s Hospital in Boston, with institutional review board approval, and under an investigational device exemption protocol filed with the US Food and Drug Administration. Informed parental and/or patient consent was obtained in all cases. Patients were selected for consideration of stent implantation if they had significant stenoses in branch pulmonary arteries, right ventricular–pulmonary artery conduits or pulmonary outflow tracts, or systemic veins, including Fontan anastomoses and other postoperative venous channels. In patients in whom unilateral pulmonary artery stent placement was planned, lung perfusion scan was done.

Overall, there were 49 males and 36 females, aged 0.9 to 36.2 years (mean±SD age, 13.1±8.3) and weighing 7.4 to 79.0 kg (mean weight, 40.0±20.0 kg). The PalmaZ® stent (Johnson and Johnson Interventional Systems, Sommerville, NJ) was used in all patients. Most stents were 3 cm long with a 3.4-mm nominal outer
FIG 1. A, Severe bilateral branch pulmonary artery stenoses at the distal end of a conduit in a patient with pulmonary trunk atresia and ventricular septal defect. Placement of a stent in one proximal orifice was expected to cut off catheter access to the contralateral artery. B, 11F sheaths were placed in right and left pulmonary arteries, and the right pulmonary artery stent (arrowheads) was installed first. The left pulmonary artery stent was advanced through the other sheath into position (curved arrow). C, During inflation of the left pulmonary artery stent, the right pulmonary artery balloon was inflated. This served to keep the mouth of the right pulmonary artery stent from being compressed by the other balloon and protected the left pulmonary artery balloon from being cut and ruptured by the relatively sharp proximal ends of the previously expanded stent. D, Follow-up angiogram in the same projection and magnification showed marked improvement of both right and left stenoses.
diameter ("iliac"); four were 2.0 cm long and 2.5 mm in diameter, originally designed for renal use. Two stents were specially made "iliac" stents: one 12 mm long and one 20 mm long.

The technique of percutaneous implantation has been described previously. Briefly, a stenotic lesion was dilated in usual fashion with a balloon angioplasty catheter. If the stenosis was dilated with the balloon and then recoiled to its original inadequate size, stent placement was considered. After the activated clotting time was measured, a loading dose of 50 units/kg heparin was given, and additional heparin was given to
maintain the activated clotting time value at twofold to threefold control. Heparin (3 units/mL) was added to the flush solution and to the contrast material, iohexol 350 IU/mL. With a 0.038-in. SuperStiff® wire (Medi-Tech, Mansfield, Mass) well across the narrow area and deeply anchored in the lung or vessel distal, a long 11F sheath (8F for renal stents) was advanced distal to the target area. The stent was loaded by hand onto the balloon catheter and pressed firmly onto the middle of the balloon. The stent-balloon assembly was inserted into the sheath carefully to prevent dislodging the stent during its passage through the sheath’s hemostasis valve. The stent on the balloon was advanced through the sheath and centered on the lesion. Only then was the sheath withdrawn off of the balloon and stent. At that point, an angiogram was performed with a second venous catheter to confirm the exact location of the stent in relation to the stenosis. The balloon was inflated to the recommended inflation pressure, expanding the stent and anchoring it in place. With the wire left in place, redilation was performed using a larger diameter balloon, where indicated. Finally an end-hole catheter was inserted over the wire through the stent lumen to remove the wire without pulling it past the freshly implanted stent. Postimplantation pressure measurements and angiography were performed. Cefazolin (12.5 mg/kg) was given intravenously for the first of four doses.

The day after the catheterization, chest radiograph, echocardiogram, and (where necessary) radionuclide lung scan were repeated; then, the patient was discharged. Aspirin 80 or 325 mg once daily and dipyridamole 1 to 2 mg · kg⁻¹ · day⁻¹ in two or three divided doses were prescribed for 6 to 12 months after implantation. Some investigators (S.B.P. and J.E.L.) recommended warfarin instead of antplatelet drugs for anticoagulation.

Special Implant Techniques

Series placement. In some patients, stenoses were of such length (more than 2 cm) that series placement was required. In these cases, one stent was placed at the stenosis or at the distal part of a long narrowing. If there were significant residual stenosis at one end of the stent, a second stent was implanted using the same wire and sheath, overlapping the first stent several mm. The patient with a long superior vena cava stenosis had virtual obliteration of the cava/systemic venous atrial junction as a consequence of an earlier Mustard operation. From a right internal jugular vein approach, a long sheath and dilator were positioned in the stump of the obstructed superior vena cava. The sheath and dilator were then advanced into the systemic venous atrium over a transseptal needle, which was used to puncture the atritic vein segment. Once the dilator was in place, a wire was left in the atrium, and sequential balloon dilation of the stenosis was done, followed by removal of the pacing wire and implantation of four overlapping stents. This resulted in a widely patent channel from high superior vena cava to the atrium.

Simultaneous placement. In four cases, bilateral branch stenoses were present, and one or both stenoses were very proximate to the main pulmonary artery. Unilateral stent placement could block catheter (and stent) access to the contralateral arterial narrowing. A technique was devised by one of the investigators (C.E.M.), whereby bilateral wires and 11F sheaths were placed into the branch pulmonary arteries. Stents were loaded onto separate balloon catheters and positioned across right and left branch narrowings. First, one balloon/stent combination was inflated, anchoring that stent. Then, the balloons were inflated simultaneously, implanting the stent and the stent from being ruptured by the relatively sharp proximal ends of the expanded first stent (Fig 1). If one or the other stent required further dilation, then it was useful again to cushion the larger balloon by reinflating the opposite dilating catheter at the same time. This approach enabled the implantation of stents in cases of bilateral stenoses at the ends of conduits or outflow tract patches.

Parallel implantation. The third modification, placing the stents in parallel simultaneously, was used in one patient. In this case, the right upper and middle lobe branches were stenotic at their origins from the right pulmonary artery. There was concern that placing either of the stents might compromise the other branch pulmonary artery. Two 7F sheaths (for renal stents) were advanced across the middle and upper lobe stenotic areas. When the balloon/stent combinations were in position, the balloons were inflated simultaneously. The proximal ends of the stents appeared to contact each other for several mm, which did not affect the patency or efficacy (Fig 2).

Surgical placement. One patient with severe progressive idiopathic branch pulmonary artery stenosis had developed complete atresia of right middle and lower lobe branches and was documented to have 80% of flow to the severely narrowed left pulmonary artery. During sheath placement alone, the patient became bradycardic and hypotensive. A hurried attempt to place a stent resulted in proximal migration and inflation of the stent in the main pulmonary artery. This device was removed at surgery, and with the patient supported with cardiopulmonary bypass, a new stent was inserted into the narrow left pulmonary artery under direct vision. The stent was loaded onto a 10-mm-diameter balloon catheter as usual; the stent and balloon were placed in the left lung artery orifice by the surgeon; and the balloon was inflated. A 12-mm balloon was then used to flare the protruding proximal end of the stent slightly to flatten it against the main pulmonary artery wall and preserve catheter access to the right pulmonary artery.

Left pulmonary artery placement. Because of the S-shaped curve required to negotiate the course from inferior vena cava through the right ventricle to the left pulmonary artery, the right branch has proven a technically easier target. It has been very important to put the stiff guide wire well into the pulmonary artery, with the stiff part forming an arch past the stenotic area, to avoid the recurring problem of the sheath’s backing out of the left pulmonary artery and losing access to the stenosis. Often, the wire is difficult to reposition at that point. An approach from the right internal jugular vein has been performed successfully in two patients by one of the authors (J.E.L.), as a method to straighten out the entry to the left pulmonary artery in such cases.

Choice of stent and balloon catheter shaft size. Stent sizes varied, depending on whether they were designed for the iliac artery (3 cm length, 3.4 mm outer diameter) or renal (2 cm, 2.5 mm). Because of the weakness at the
FIG 2.  A, Right middle and lower lobe branches showed severe stenosis. Placement of a stent in one branch was thought to risk compression and iatrogenic narrowing of the other vessel. Stents were placed simultaneously through two sheaths in these areas. B, Right middle and lower lobe pulmonary artery stents (arrows) showed excellent patency after simultaneous placement. The magnification in Fig 2, B is slightly greater than that in Fig 4, A.
center joint bar in the articulated version of the stent, nonarticulated stents were used almost exclusively. The theoretical problem of stiffness of the stent and difficulty in negotiating curves and bends were not an impediment in this investigation. The future availability of stents cut and machined by the manufacturer to specific sizes will allow a wider choice of stents for a greater variety of uses. With the use of low-profile balloons, care must be taken to choose a catheter for stent delivery that will permit the stent to be crimped firmly onto the catheter. For example, a 7F-shaft 12-mm balloon catheter will allow an iliac-sized stent to be mounted securely, while the same stent will slide off of the balloon of a 5F 12-mm catheter, preventing delivery.

**Statistical Analysis**

Values were expressed as mean±SD. Preplacement and postplacement data were compared using a paired two-tailed Student’s t test. Results were considered significant if P≤.05.

**Results**

**Pulmonary Artery Group**

Eighty stents were placed in pulmonary arteries in 58 patients (age, 1.2 to 36.2 years; median, 11.8; weight, 9.1 to 79.0 kg; mean, 40.1; median, 44.4). Forty-five patients had postoperative tetralogy of Fallot or tetralogy of Fallot with pulmonary atresia, 3 had postoperative truncus arteriosus, 5 had right pulmonary artery stenosis at the site of a previous pulmonary artery band, and 5 had native branch pulmonary artery stenosis. Prior to dilation and stenting, the vessel diameter was 4.6±2.3 mm, and it increased to 11.3±3.2 (P≤.0001) (Fig 3, A). Systolic pressure gradient across the stenoses fell from 55.2±33.3 to 14.2±13.5 mm Hg (P≤.0001) (Fig 3, B). In patients with intact ventricular septum, right ventricular–femoral arterial systolic blood pressure ratio decreased from 0.69±0.23 to 0.43±0.15 (P≤.0001). In 36 patients with unilateral stent placement who had presten and poststen nuclear medicine pulmonary perfusion scans, the percentage of flow to the ipsilateral lung rose from 29.4±16.4% to 51.1±13.3% (P≤.0001). In 18 cases, presumably because of increased resistance in the high-flow contralateral pulmonary bed, the flow percentage to the stented lung was more than 50%.

**Venous group.** Twenty-one patients aged 0.9 to 30.3 years (mean, 14.3; median, 16.3; weight, 45.4±21.2 kg; range, 7.4 to 72) had stents placed in veins or venous anastomoses. Twenty-eight stents were used, with two devices implanted in four instances and four placed in series in the one individual with a long-segment stenosis of the superior vena cava. One patient had one stent in a Fontan anastomosis and another in the left pulmonary artery. Mean pressure gradients fell from 9.8±6.9 to 2.4±3.1 mm Hg (P≤.0001), and diameter of the narrowings improved from 3.8±2.9 to 11.3±2.8 mm (P≤.0001) (Fig 4). In two of three patients with superior vena cava syndrome, signs and/or symptoms resolved promptly in one case, showing improvement within 18 hours (Fig 5).

**Conduit group.** Nine stents were implanted in conduits or right ventricular outflow tracts in six patients. Three patients had postoperative tetralogy of Fallot, with or without pulmonary trunk atresia. There were two postoperative truncus patients, and one patient who had postoperative conduit repair for complex heterotaxy with pulmonary trunk atresia. Patient age ranged from 3.5 to 25 years of age (mean, 9.9; median, 7.2) and weighed from 13 to 55 kg (mean, 31.2). Stenosis diameter increased from 8.8±3.6 to 12.7±2.6 mm (P≤.005), and pressure gradient fell from 41.4±26.0 to 20.7±17 mm Hg (P≤.01) (Fig 6). Right ventricular–femoral arterial pressure ratio declined from 1.0±0.2 to 0.74±0.2 (P≤.0001).

**Complications**

Major complications included six embolized or malpositioned stents and two deaths within 1 week of
FIG 5. A, Lateral cineangiogram of a patient with severe superior vena cava stenosis after repair of partial anomalous pulmonary venous return. The catheter position marks the right atrium/superior vena cava junction, through which only a thin line of contrast passed (arrow). A large and tortuous azygous vein was seen to drain the superior vena cava through a pathway that circumvented the stenosis. B, After dilation and stent implantation, the stent was seen to buttress the open superior vena cava/right atrial junction (arrow). The junction was widely patent. There was immediate disappearance of the azygous pathway.
FIG 6.  A, Conduit stenosis diameters before and after stent implantation are shown. Circles and arrow bars represent mean and SEM values. There is a modest but significant increase in the stenosis and the diameters of the stenotic segments. Two patients with essentially the same diameters before and after stent implantation had mild-to-moderate stenoses that were difficult to expand fully with balloon dilation, either alone or with stent placement. In retrospect, stents likely should not have been placed in these two stenoses. B, Pressure gradients before and after stent implantation in conduits are shown, with mean and SEM values in the margins. One patient whose gradient did not change had little increase in stenosis and a possible mild increase in cardiac output during the catheterization. In the others, there was a small but consistent and significant fall in the gradients.

catheterization. One postoperative Fontan patient who died had undergone technically correct left pulmonary artery stenting and developed progression of a preexisting right atrial clot and fatal pulmonary embolism the night after catheterization. That patient was described in an earlier report.2 The second patient had complex heterotaxy with ventricular inversion and pulmonary stenosis. A stent was placed in the ventricular to pulmonary artery homograft in the early postoperative period to treat severe obstruction in the ventricular/conduit junction. The stent provided a widely patent outflow tract (and stented the homograft valve open, causing free regurgitation); the patient died 1 day later. Post mortem showed a patent stent with no distortion or thrombosis.

In this series, six stents (5%) were positioned incorrectly or embolized. In two of the first three patients enrolled in the protocol, stents were attempted to be placed in right ventricular outflow tract stenoses, which proved too patulous to allow the devices to be seated and anchored properly. Another two patients had a stent become free in the right ventricle when the inflating balloon milked back during expansion. This action brought the stent proximal to the narrowing and resulted in its becoming loose in the ventricle. These four stents were removed at surgery urgently, although they caused only asymptomatic ectopic beats. During surgical stent removal, the surgeon revised the outflow tract where indicated. One stent that had milked proximally into the right atrium in a Fontan patient was crumpled by means of wire retrieval baskets and then removed percutaneously through a 24F sheath. As described previously, one device that moved distally into the nonstenotic portion of the left pulmonary artery in a Fontan patient was reexpanded against the normal artery and left in place without sequelae.1 Afterward, the stenosis itself was stented successfully.

Minor Complications

Minor complications were few. There was one instance of small vessel arterial rupture and two of side-branch occlusion.1 No systemic emboli occurred. On follow-up, one stent in the proximal end of the right ventricular to pulmonary artery conduit was found to have fractured into three pieces. One piece remained in place, whereas two embolized to the left pulmonary artery without causing obstruction to flow. This stent, which had a residual waist on initial implantation, had a high-pressure balloon used to try to expand the stent further. This caused an asymmetric expansion that, in conjunction with the fact that the proximal end of the stent was juxtaposed to beating myocardium, may have caused the metal to develop stress fractures. The fragments were left in place, and the patient, who was refused for repeat surgery because of high risk, underwent repeat stent placement at the follow-up catheterization. The replacement stent has not shown fractures in 6-month follow-up. One stent in a right pulmonary artery developed a longitudinal break during redilitation with two high-pressure balloons (16 atm) side-by-side. This did not result in restenosis, stent collapse, or extravasation. No additional stenting or treatment was required. No other stents in this series have developed fractures detectable on radiograph or at recatheterization.

Follow-up

Patients have been followed for 3 to 27 months (mean, 11.3), a total of 80 patient-years. No thromboses have been detected in any patient, regardless of anticoagulation regimen. Three patients died, at 3 weeks, 4 weeks, and 24 months after stent implant. The first died suddenly from complications of heart disease unrelated to the stents (double outlet right ventricle with pulmonary atresia). Post mortem examination demonstrated a patent stent with no evidence of thrombosis. A second patient died 4 weeks after stent placement and 4 weeks after surgical repair of double outlet right ventricle with pulmonary atresia and discontinuous pulmonary arteries. He had had a stent placed 1 day after surgery because of severe left pulmonary artery stenosis and suprasystolic right ventricular pressure. The stent procedure resulted in a fall in right ventricular pressure to one half systemic. The patient nonetheless developed respiratory distress syndrome and required extracorporeal membrane oxygenation. The stent was widely patent and in good position at post mortem. The third patient was 15 years after surgical tetralogy of Fallot repair and had developed right ventricular dysfunction and atrial flutter requiring a pacemaker. He had had a 3-month postimplantation catheterization with excellent appearance of the stents. He died suddenly at home 2 years after stenting; post mortem was not performed.

Recatheterization

Thirty-eight patients have undergone recatheterization, 1 day to 24 months after implant (mean, 8.6 months), a follow-up total of 27.2 patient-years. Twen-
took place from 1 week to 24 months after placement (mean, 10.2 months). The indication for reexpansion was a residual waist in the stent (and the one restenosis) or the need for a larger diameter arterial segment. In nine cases, redilation was carried out with standard-pressure balloons; high-pressure catheters (using ≥10 atm pressure) were required in the other eight cases. The narrowest diameter of the stents increased from 9.0±2.6 to 11.8±2.2 mm (P≤.01), and the systolic pressure gradients decreased from 20.4±16.5 to 10±12.1 mm Hg (P≤.01) (Fig. 7). There was one instance of stent fracture (see above) due to vigorous redilation with two high-pressure balloons placed side-by-side in the right pulmonary artery stent. There were no other untoward effects from redilation. Two patients had additional stents placed at recatheterization. The new devices were placed in contralateral pulmonary arteries. The presence of one or more pulmonary artery stents did not interfere with additional stent installation.

Discussion

In this report, description of a large number of stent procedures and considerable intermediate-term follow-up data have been presented. This represents both a more extensive experience and longer-term follow-up than ever previously documented in congenital heart disease. These early and intermediate-term results have continued to be promising and gratifying. There were no thromboses and only one instance of restenosis due to intimal hyperplasia. Patient selection has been important, with the most favorable candidates being adult or adolescent-sized patients with discrete single branch pulmonary artery stenosis because of technical ease of implantation and ability to dilate to a size appropriate for an adult. The relatively older age and large size of the patients reflected the authors’ concern that long-term effects are unknown, and that redilation, although possible to a limited degree, has not been ensured. There still is no information that this will be possible after years to account for the growth of smaller patients.

From the results of the present study, it is suggested that placement of stents within or adjacent to the ventricular myocardium be reserved for cases with no surgical alternatives. The results in the conduits group are not as encouraging as in the other two groups, and fracture has occurred in one stent that extended from right ventricle to main pulmonary artery. The sometimes patulous nature of the distented outflow tracts makes poor seating and embolization more likely. Indeed, in most cases, unlike the distal branch pulmonary arteries, the pulmonary outflow tract and conduit regions are accessible to the surgeon. The results reported for conduits by Hosking and colleagues2 are similar, and those investigators suggest this type of implant may be only a temporizing maneuver.

It has been shown that stents can fracture with high-pressure balloons used in tandem. The right ventricular outflow tract stent that was fractured on follow-up evaluation had been dilated previously with a high-pressure balloon in an attempt to eliminate a residual stenosis. If a waist remains on a standard (3 to 6 atm) balloon during predilation, then a stent, which has no additive dilating power, should not be implanted. It is suggested that if high-pressure balloons are to be used, they are implemented in the present dilating

FIG 7. A, Diameters of stenoses after stent implantation are shown in the first column compared with their diameters at follow-up catheterization. The small changes likely were due to differences in measurement technique and are not significant statistically. After redilation, there was a small but significant increase in the diameters. B, Follow-up pressure gradients are shown at the end of stent placement at follow-up catheterization and after redilation. There was no statistically significant difference between the gradients after implantation and at follow-up catheterization. Some measured gradients increased slightly, and others fell, likely due to differences in the physiological state during catheterization. After redilation, there was a significant decrease in measured gradients across the stenoses. All patients showed no change or a decrease in gradient after redilation except one. In this patient, there was clinical evidence of improvement in cardiac output.

Redilation

Within 24 months of initial implant, attempts were made to redilate 17 stents in 14 patients. The redilations
procedure, to relieve a resistant stenosis. Once the stenosis has been broken by the higher-pressure balloon, the stent may be implanted and dilated with the low-pressure balloon. Caution should be exercised to ensure that after high-pressure dilation, there is still enough residual stenosis on which to anchor the stent and minimize the risk of embolization.

Conclusions

We conclude that balloon-expandable intravascular stents are very effective in treatment of vascular stenoses in congenital heart disease. Careful selection of patients remains the main determinant of successful application of this new therapy. Stents have shown lasting patency and some limited ability to be redilated in short- and medium-term follow-up. They appear to be extremely effective in lesions that are difficult or impossible to treat surgically and in high-risk patients or those who have been turned down for surgery. On the other hand, they have been rarely successful in significant conduit stenosis. Further clinical use and follow-up will be necessary to determine the long-term benefits and risks of these devices.

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