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PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Pulmonary Artery Stents in the Recent Era: Immediate and Intermediate Follow-Up

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Background: Long-term follow-up after stent dilation of native and acquired pulmonary artery stenosis is scarce in the pediatric population. Most cohorts include a myriad of anatomies and associated conditions. **Method**: In order to establish objective performance criteria, we performed a retrospective review of all patients who underwent unilateral pulmonary artery stenting in biventricular physiology at three centers from June 2006 to June 2011. **Results**: Fifty-eight patients received 60 stents with Palmaz Genesis stent used most commonly (78%). Average age at implantation was 10.4 ± 10.3 years and weight 31.6 ± 21.8 kg. The immediate success rate was 98%, with improvement in minimal diameter from 5.1 ± 2 cm to 10.6 ± 3 cm ($P < 0.01$). There were 10 complications (7 major and 3 minor) and no acute mortality. One-year follow-up studies were available in 48 patients (83%), including echocardiogram (60%), catheterization (28%), MRI (29%), and lung perfusion (31%). Follow-up echocardiogram showed mild increase in stent gradient, from 5.7 ± 6.7 mm Hg post-procedure to 17.1 ± 11.7 mm Hg. Follow-up catheterization showed no significant change in minimal stent diameter (8.8 ± 2.6 to 7.8 ± 2.3 mm), gradient (7.7 ± 8.4 to 12.6 ± 12.2 mm Hg), or right ventricular pressures (43.7 ± 9 to 47.7 ± 10.5 mm Hg). Nine patients (16%) underwent scheduled stent redilation over a period of 12 days to 25 months. **Conclusion**: In conclusion, stent implantation shows excellent immediate and 1-year follow-up results with maintenance of improved caliber of the stented vessel and lowered right ventricular systolic pressures.

Key words: congenital; stenosis; outcomes; complications

BACKGROUND

Branch pulmonary artery stenosis is a frequent yet challenging lesion, seen in both native and acquired forms. In the pediatric population, it can be seen either as an isolated lesion, or more commonly associated with genetic syndromes and other forms of congenital heart disease. Surgical repair may itself cause or exacerbate pulmonary artery stenosis secondary to scar formation, vascular distortion, folding or external compression, with a recurrence rate of 35–40% [1–3]. Unless treated early in life, long standing stenosis of one or both pulmonary arteries can lead to poor distal vascular growth as well as right ventricular hypertension and progressive pulmonary insufficiency [4–14].

Since the advent of angioplasty and stent implantation in the late 1980s, there has been a gradual shift from surgery to a percutaneous approach. To date,

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TABLE I. Baseline Patient Characteristics at the Time of Intervention

Pre stent data	Mean ± SD
Age (years)	10.4 ± 10.3
Weight (kg)	31.6 ± 21.8
Height (cm)	124.1 ± 33.4
BSA (m^2)	1 ± 0.4
Gender (male:female)	30 (52%):28 (48%)
Site (left:right)	43 (74%):15 (26%)
MRI parameters (available in 16 patients)	
Indexed RV volume (ml/m^2)	123.1 ± 25.7
RV ejection fraction (%)	50.4 ± 6.8
Regurgitant fraction (%)	34.4 ± 16

TABLE II. Primary Diagnosis

Primary diagnosis	*N* (%)
Tetralogy of Fallot	30 (52%)
Pulmonary atresia-VSD	6 (10%)
Truncus arteriosus	3 (5%)
Transposition of the great arteries	2 (3%)
Double outlet right ventricle	2 (3%)
Pulmonary atresia with intact ventricular septum	2 (3%)
Pulmonary stenosis	2 (3%)
Others	11 (19%)

there are over 20 outcomes publications on the use of stents to treat pulmonary arteries providing excellent early results [4–6,14–18]. However, mid- and long-term follow-up studies evaluating the effects of angioplasty and stent implantation are scarce [4,14–17]. Outcome metrics of these publications are not uniform with a mixture of two ventricle and single ventricle patients, unilateral and bilateral stenosis as well as serial stenosis involving various lobar, segmental, and subsegmental branches rendering difficulty to define accurately objective performance criteria for this procedure. In order to limit the variables of the pathology, we analyzed the immediate and 1-year follow-up of stent implantation to treat biventricular patients with unilateral pulmonary artery stenosis with the goal to establish objective performance criteria for stent therapy in pulmonary artery stenosis. In addition, there has been an improvement in stent technology such that older stents (Palmaz XD stent) used widely in the 90s have been replaced by newer stents (Genesis XD and MaxLD stents) in the 2000s. Hence, we only evaluated patients who met the inclusion criteria within the recent past in order to assess the outcomes of the newer stents which are being employed in the current era.

METHOD

A retrospective review was performed of all two ventricle patients who underwent unilateral pulmonary artery stenting from June 2006 to June 2011 at three centers: Texas Children's Hospital, Children's Hospital of Michigan, and the Mayo Clinic. Exclusion criteria included bilateral or additional distal branch pulmonary artery angioplasty or stent implantation, concomitant right ventricle (RV)-pulmonary artery (PA) conduit intervention, single ventricle physiology with or without palliation, and genetic syndromes associated with congenital branch pulmonary artery stenosis, e.g. Alagille and Williams syndromes. Procedural success was based on previously published data for angioplasty which includes: (1) >50% improvement in vascular diameter, (2) >50% decrease in gradient across the stenosis, (3) >20% reduction in the right ventricle-to-systemic artery systolic pressure ratio, or (4) a 20% increase in flow to the affected lung [19].

Demographic data, pre- and post- procedural imaging including echocardiograms, lung perfusion scans, and cardiac imaging (CTA or MRI when available), as well as hemodynamic and angiographic data were collected. Stent selection was based on individual and institutional preference. Continuous data were represented as mean ± standard deviation. A two-tailed *t*-test was used to assess differences amongst continuous data. A *P*-value of <0.05 was considered statistically significant.

RESULTS

Patient Profile

One hundred and eighty-eight pulmonary artery stent implantations were performed in the 5 year period, of which 58 patients met inclusion criteria in the three centers from June 2006 to June 2011. The mean age of the patients was 10.4 ± 10.3 years (51.7% males). Baseline characteristics of the patients are listed in Table I. Fifty-six patients had a previous operation for congenital heart disease, Tetralogy of Fallot being the most common lesion (52%). Isolated pulmonary stenosis without any other form of congenital heart disease occurred in only five patients (8.6%, Table II). Left pulmonary artery was involved in 43 patients (74%, Table I). Sixty stents were implanted in 58 patients, with Palmaz Genesis stent used most commonly (47 stents, 78%). Other stents used were Covidien (formely EV3) stents (8 stents, 13%), Valeo premounted stents (3 stents, 5%), and Palmaz stents (2 stents, 3%).

Cardiac Catheterization Data

The pre- and post- intervention hemodynamic and angiographic data are listed in Table III. The overall implantation success rate was 57 in 58 patients (98%); only one patient had suboptimal result due to stent

TABLE III. Hemodynamic and Angiographic Data at the Time of Stent Placement

	Pre-stent[a]	Post-stent[a]	P value
Right pressure (mm Hg)	44.2 ± 15.5	41.4 ± 14.3	<0.01
RV:FA ratio (%)	52.3 ± 20.2	45.1 ± 16.5	<0.01
MPA:branch PA gradient (mm Hg)	18.1 ± 10.4	5.8 ± 7	<0.01
Stenosis diameter (mm)	5 ± 1.9	10.7 ± 2.9	<0.01
Stenotic PA:contralateral PA (%)	38 ± 16	84 ± 44	<0.01

[a]Mean ± SD.

TABLE IV. Complications

Complications	No. of patients (%)
Major	7 (12%)
Stent migration/embolization requiring treatment	2
Hypotension requiring inotropes	1
Reperfusion injury requiring treatment	1
Suspected thrombus in RVOT	1
Local vascular thrombosis	1
Left recurrent laryngeal nerve injury	1
Minor	3 (5%)
Stent migration	1
Dissection	1
Bradycardia—no treatment required	1

embolization requiring surgical repair later. A second patient underwent angioplasty initially but lost wire position and decision was made to abort the stent procedure. This patient was brought back to the cath lab at a later date and underwent successful stent implantation in the left pulmonary artery (LPA).

The average right ventricular pressure was 44.3 ± 15 mm Hg preintervention, with a RV-to-femoral artery systolic pressure (FA) ratio of $52 \pm 19.5\%$. Pre- and post-intervention RV-to-FA pressure ratios were obtained in 51 patients, with a significant improvement to $44.9 \pm 16.4\%$ post-intervention ($P < 0.01$). Pre- and post-intervention gradients across the stenosis were available in 40 patients, showing a significant improvement from 18.1 ± 10.4 mm Hg at baseline to 5.8 ± 7 mm Hg post stent implantation ($P < 0.01$). Angiographically, the stenotic pulmonary artery segment improved from 5.1 ± 2 cm to 10.6 ± 3 cm ($P < 0.01$), with an average of $231 \pm 84\%$ increase in vessel diameter. When comparing the diameter of the stenotic segment to the contralateral pulmonary artery, the ratio improved from $37.6 \pm 16.3\%$ to $84.5 \pm 44.1\%$ ($P < 0.01$, $n = 46$) post stenting.

Complications

There were 10 complication (17%) overall (7 major and 3 minor) and no acute mortality. Major complications included stent migration (2), dissection (1), transient hypotension (1), thrombosis requiring treatment (2), reperfusion injury (1), and recurrent laryngeal nerve palsy (1). Minor complications included stent malposition (1), minor dissection and aneurysm not requiring treatment (2). Of the two major stent migrations, one had a proximal stent migration but was repositioned and restented successfully using a second stent during the same procedure. The other underwent surgical repair along with conduit revision 4 days later. There was one instance of minor stent malposition which had no anatomical or hemodynamic consequence. One patient had a small, contained dissection post-angioplasty where a stent was used to tack down the intimal flap. No further complications on follow-up studies were observed on this patient. One patient had hypotension during induction of anesthesia requiring temporary inotropic support for the procedure.

One patient developed a femoral venous thrombus at the sheath insertion site, which resolved with heparin therapy. The 1-year follow-up did not reveal any sequelae. Further complications are noted in Table IV.

Follow-up

The median length of post-procedure hospital stay was 2 days, ranging from 0 to 60 days. Fifty patients (85%) had a length of stay ≤ 2 days. One patient was hospitalized for 60 days post-procedure due to pulmonary hypertension and ventricular tachycardia and eventually expired. The cause of death was unrelated to the procedure or stent implantation. There were no other mortalities during the post-procedure hospital stay.

Some form of follow-up studies one year or later after the initial procedure were available for 48 patients (83%). These included echocardiograms, cardiac catheterization, pulmonary perfusion scans, MRI or CT angiography. Eight patients (14%) were lost to follow-up or were transferred back to their primary cardiologist, outside of the three institutions.

Cardiac Catheterization

Sixteen patients (28%) underwent follow-up catheterization at median follow-up of 14 months (range 3 months to 4 years) post-intervention. This data excludes the single patient who returned to the cath lab one day later for repositioning of a malposed stent.

Indications for repeat catheterization included stent further dilation in nine, for conduit or contralateral pulmonary artery stenosis in three, elective electrophysiology or hemodynamic study in two, and hybrid approach for redilation at time of reoperation in two. Follow-up cath data showed no significant decrease in minimal diameter of the stent (8.8 ± 2.6 to 7.8 ± 2.3 mm, $P = 0.4$, $n = 8$), increase in gradient

TABLE V. Follow-up at 1 Year

	Cath pre-stent[a]	Cath post-stent[a]	At 1 year (Echo f/u)[a]
RV pressure (mm Hg)	44.19 ± 15.28	41.11 ± 14.32	36.08 ± 11.07
RV:arterial systolic ratio (%)	51.61 ± 19.49	44.92 ± 16.42	34.39 ± 12.36[b]
Gradient (mm Hg)	19.02 ± 10.45	5.70 ± 6.73	17.12 ± 11.67
Diameter (mm)	5.1 ± 2	10.7 ± 3	9.7 ± 2.7

[a]Mean ± SD.
[b]Arterial pressure based on cuff measurements.

(7.7 ± 8.4 to 12.6 ± 12.2 mm Hg, $P = 0.33$, $n = 9$), or increase in right ventricular pressures (43.7 ± 9 to 47.7 ± 10.5 mm Hg, $P = 0.2$, $n = 12$). Nine patients (16%) underwent scheduled serial stent further dilation over a period of 12 days to 25 months (mean 13 ± 26 months). Two of these were intraoperative interventions at 12 days and 25 months, respectively. In both cases, the primary indication for the surgery was RV-PA conduit intervention. There was one stent fracture noted 1 month after stent redilation (26 months after initial procedure) with no significant restenosis noted on follow-up echocardiograms. No other stent fractures were noted at follow-up.

Echocardiogram

Pre-procedural echocardiograms were available on 54 patients (93%). Majority of the patients had normal right ventricular function. Of the four patients with no available pre-procedural echocardiogram data, three had alternative imaging available (MRI or CT angiography), while one patient referred from an outside institution did not have echocardiogram available for review.

Echocardiograms at 1 year were available on 35 patients (60%). There was only mild increase in gradient across the stent from 5.7 ± 6.7 mm Hg post-procedure to 17.1 ± 11.7 mm Hg upon follow-up (Table V). Unfortunately, accurate assessment of the luminal diameter in the stented region was hampered by artifact in large proportion of the patients.

Cardiac MRI

Cardiac MRI was obtained in 17 (29%) patients prior to catheterization. Initial right ventricular function was normal to mildly depressed in all patients, with indexed right ventricular volume of 123.1 ± 25.7 ml/m^2. Unfortunately, only five of these patients had a follow-up MRI, obtained 1–2 year after the procedure. Indexed right ventricular volumes, ejection fraction, and regurgitant fractions remained unchanged upon follow-up. Assessment of the stented pulmonary artery segment was not possible due to artifact interference by the metallic stents.

Lung Perfusion Studies

Post-intervention perfusion evaluation was performed in 24 patients, by nuclear scans ($n = 18$) and MRI ($n = 6$). Pre- and post-intervention assessment of lung perfusion was available in 15 patients: by nuclear scan (4), MRI (5), or a combination of both (6), (26%). Median follow-up of these 15 patients was 312.5 days (range 2 days–1070 days). There was a significant improvement in perfusion in the affected lung from 19.6 ± 9.1% to 35.5 ± 6.1% upon follow-up.

DISCUSSION

Treatment for branch pulmonary artery stenosis includes surgical repair, angioplasty, and stent implantation. A search of the literature indicates that surgical reports are scant and results are poor with a recurrence rate of 35–40% [1–3,20–23]. Angioplasty alone showed a success rate of 50–60%, with a recurrence rate of 15% and complication rate of 6–12% [2,19,24]. Recent studies using high pressure and cutting balloons, alone or in combination, have shown promising results in immediate improvement when used in resistant lesions, especially in younger patients [25–29]. However there remain issues with recoil resulting in reduced interval growth. Studies evaluating the effects of stent implantation report success rates as high as 90% [16–18]. However the heterogeneity of pathology in pulmonary artery stenosis (single vs. biventricular physiology, proximal vs. distal pulmonary arteries, unilateral vs. bilateral stenoses, post surgical vs. congenital) renders difficulty in outcome analysis due to the variable physiology and response of these lesions to intervention [30]. In our study, we focused on lesions limited to unilateral, proximal branch pulmonary arteries in order to provide a more homogenous population for analysis. We also limited the study to the recent past (2006–2011) in order to study the outcomes of the newer stents being used currently.

The overall technical success rate was 98% amongst the three centers involved in this study, with significant improvements in vascular diameter, pressure gradients, right ventricular pressure along with concomitant improvement in regional perfusion to the stented lung. Our study showed an overall 17% procedural complication rate of which 12% are in the major category. Review of the literature suggests pulmonary artery stent complication rates ranging from 10% to 33% [2,18,31–34]. However, given the diversity of patients, heterogeneity of pulmonary artery stenoses and

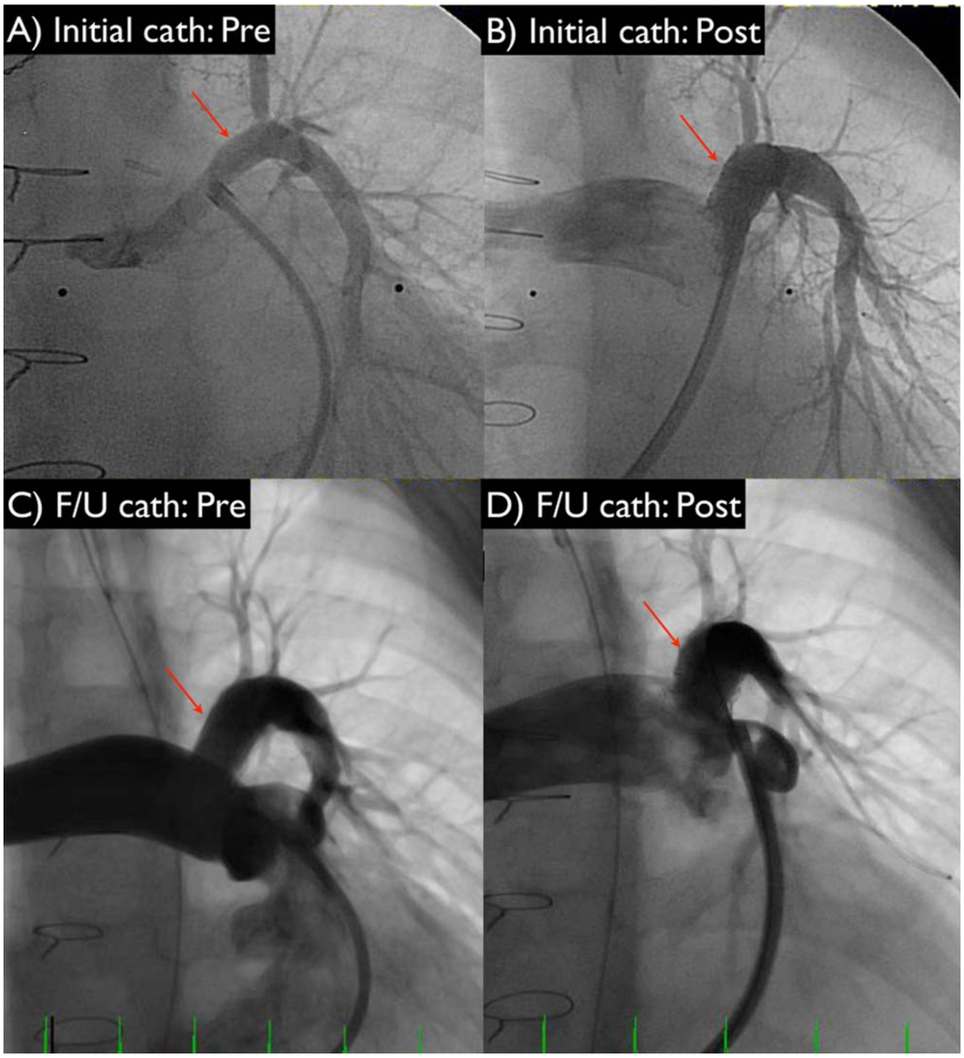

Fig. 1. Example of a left pulmonary artery stenosis associated with hypoplasia before and after rehabilitation with stent implantation (red arrows). A: Initial diameter was 3 mm. The systolic right ventricular to systemic artery pressure (RV/FA) ratio was not significantly elevated (45%). There was wide discrepancy in branch pulmonary artery flow with only 18% flow to the left lung. B: Following implantation of a Geneis stent (PG1910), the diameter increased to 9.4 and the RV/FA ratio decreased to normal range (30%). Left lung flow increased to 21% post-stenting. C: At the 18-month follow-up cath, there was minimal intimal growth within the stent. The diameter was 9.1 mm and the RV/FA ratio was 38%. D: Following further dilation with a 14 mm balloon, the diameter increased to 9.8 mm, the gradient was 3 mm Hg. A follow-up MRI now showed 28% flow to the left lung. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

changing technology and stent implantation techniques over time, it is difficult to compare complications between studies.

In our study, the improvement in vessel caliber and regional perfusion was relatively well-maintained upon 1-year follow-up studies when available (Fig. 1). Furthermore, qualitative analysis of the follow-up studies showed interval growth of the distal pulmonary vasculature in all but one who required angioplasty later due to progressive distal stenosis. This phenomenon is also reported in a study by Takao et al. [35]. In that article, upper and lower lobar branches on the side of the stented proximal branch had "catch-up" growth compared to the normal non-stented side in both single and two ventricle patients. Interestingly, the authors noted more growth at the lobar level for two ventricle vs. single ventricle patients. Echocardiographic evaluation of the stented vessels was the least reliable modality at follow-up. While peak velocities can be measured across a proximal branch pulmonary artery stent to estimate a gradient, it is difficult to interpret the significance of the gradients in the presence of a contralateral branch pulmonary artery that can accommodate increased flow. Furthermore, it is difficult to measure

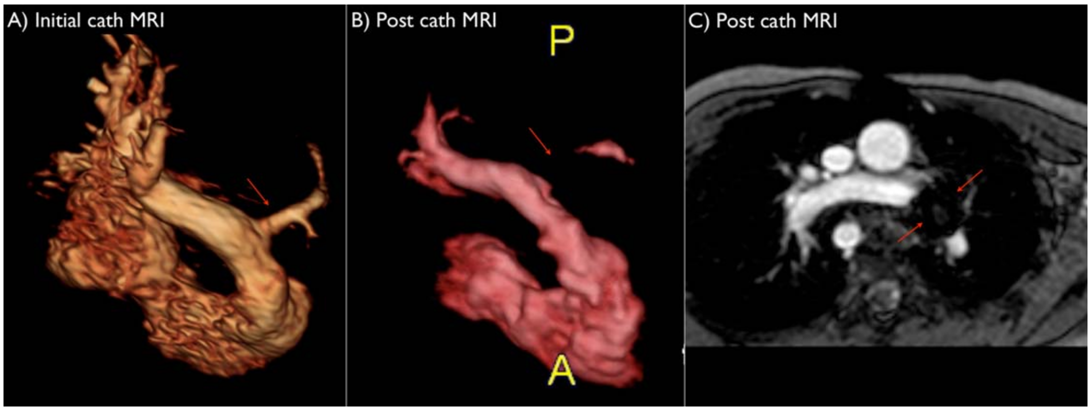

Fig. 2. MRI of same patient before and after LPA stent implantation. A: 3-D rendering showing severe stenosis and hypoplasia of LPA (red arrow). B, C: Follow-up MRI post LPA stenting showing "drop-out" artifact in the region of the stented LPA (red arrows). While relative branch pulmonary artery flow can still be derived, the stented vessel diameter cannot be measured. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

vessel diameters accurately in the presence of a stent, especially in larger patients where acoustic windows are suboptimal. Right ventricular pressures cannot be accurately measured without tricuspid regurgitation, but the interventricular septum can be qualitatively assessed to estimate the degree of right ventricle hypertension. Nevertheless, echocardiography is a useful, convenient, and non-invasive modality that can offer a qualitative assessment of the clinical status of the patient following pulmonary artery stenting. Currently, this is the standard of care for follow-up testing at many centers across the country. MRI can provide accurate information on RV size and function and lung perfusion but the stainless steel stents obscure the vascular lumen and pulmonary artery diameters cannot be measured accurately (Fig. 2). Lung perfusion scans obviously can assess the physiologic effects of the interventions but cannot provide anatomic data. CT angiograms can be used to accurately assess intra-stent diameters but does require additional radiation exposure and does not offer hemodynamic data. The most complete follow-up assessment of pulmonary artery stenting remains cardiac catheterization and angiography. However, if the patient is doing well clinically (NYHA status I or II) and there is lack of evidence of RV hypertension and significant gradients across a stented pulmonary artery, it would be difficult to justify subjecting a patient for such an invasive procedure.

Reported stent fracture rates range widely from 3% to 21% resulting in restenosis but not associated with any major hemodynamic complications. Redilation with additional stents appears to be easily accomplished [36,37]. In our series, only one stent fracture was found at the 1-year follow-up.

Limitation

The major limitations of the study include the retrospective nature of this study. The diameter measurements were made by the operating attending and fellows rather than a third party blinded physician. This data was obtained through catheterization reports and may contain bias. In addition, there is the difference in institutional protocols and operator preferences amongst the three institutions. There was a lack of consistency in pre-cath and follow-up studies between the institutions and even among operators within an institution, rendering long-term assessment of vessel growth difficult. AHA guidelines on indications for pulmonary artery stenting were published in 2011 [38], but the guidelines do not define which standard tests to use in order to establish the hemodynamic and/or anatomy criteria for stenting nor are there accepted standard testing at follow up. As such, it is assumed the data can be derived from a combination of tests including echocardiography, MRI, pulmonary perfusion scan, or CT. It is probably the latter reason that has resulted in the lack of consistency in pre-cath and follow-up laboratory data. Nevertheless, the available data we do have does show persistent improvement in the diameters of the stented branch pulmonary artery and improvement in regional perfusion.

CONCLUSION

With the recent improvement in stent design, lower profile delivery systems and greater range of stent sizes, stenting has become the preferred treatment of choice for branch pulmonary stenosis. Our data show excellent immediate and 1-year follow-up results with maintenance of improved caliber of the stented vessel and lower right ventricular systolic pressures. Close follow-up with echocardiography, MRI, CT angiography, or other perfusion studies as well as repeat catheterization may be necessary. In the growing child, further dilation will be needed until the vessels reach adult size. For residual or complex stenoses, multiple procedures will be needed to rehabilitate the pulmonary vasculature. Longer follow-up will be required to further evaluate the impact of stent implantation on vascular growth and remodeling. Equally important is the need to standardize pre-cath and follow-up testing in order to assess the hemodynamic and anatomic changes over time.

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