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Original Article

Recent results of pulmonary arterial angioplasty: the differences between proximal and distal lesions

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Abstract *Introduction:* We sought to establish a modern understanding of the safety and efficacy of transcatheter pulmonary arterial angioplasty. *Methods:* A review of records in a sample of 104 dilations, out of a total of 711 procedures undertaken between January, 1996 and December, 2000, provided descriptive information regarding technique, adverse events, and changes achieved in luminal diameter. Because evidence during the review of angiograms suggested substantial differences according to whether the stenotic lesions were positioned proximally or distally within the pulmonary arterial tree, all analyses incorporated this classification. *Results:* We reviewed stenoses in 203 pulmonary arteries, 38% located proximally and 62% distally, with follow-up available concerning dilation in 92 vessels. Proximal dilations frequently involved a prior surgical site, and appeared more compliant and amenable to conventional angioplasty, as evidenced by more common elimination of the waist, but also more recoil, then requiring placement of stents. In contrast, distal lesions frequently required balloons capable of sustaining high pressures of inflation, and larger balloons relative to the size of the vessels. The proportional increase in diameter was greater for distal sites, at 90 plus or minus 77%, compared to proximal, at 64 plus or minus 70%, p equal to 0.002. Serious adverse events occurred in 3 of 104 procedures, giving a rate of serious adverse events of 2.9%. At follow-up, 9 of 92 vessels (10%), 95% confidence intervals from 5% to 18%, returned to their diameters prior to dilation, with no difference in the rate of restenosis according to the site of dilation. *Conclusion:* Our findings indicate the need to distinguish, and to consider, the important differences in technical issues and outcomes, when performing dilations at proximal as opposed to distal sites. Although angioplasty is effective therapy for pulmonary arterial stenosis, a subset of vessels, more often distal, remain resistant to conventional techniques.

Keywords: Pulmonary trunk; paediatrics; interventional catheterisation

Pulmonary arterial stenosis may occur in isolation, but more commonly complicates serious congenital cardiac disease. Although anatomical strategies for correction have been reported for decades, new techniques and procedural changes continue to evolve.[1–9] As a result, any reliable depiction of the results of dilation must rely on the most recent available data. This requirement assumes particular importance when using existing data to help design trials intended for evaluation of novel therapies.

One such novel therapy is the recently designed Cutting Balloon (Boston Scientific, Inc., San Diego, CA). Originally developed for atherosclerotic lesions, this tool has recently been applied to pulmonary arterial angioplasty, with encouraging preliminary results.[10–12] In order to design a compelling and credible test of the hypothesis that use of cutting balloons is an improvement on existing therapy, we required a full understanding of the current results of dilations, especially the frequency of early and late events. The purpose of this study was to provide the required data.

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During the review of these data, evidence suggested a substantial difference in terms of technique, results, and adverse events between proximal lesions involving the right and left pulmonary arteries, and distal vessels, defined as the lobar and sub-lobar arteries within the pulmonary parenchyma. To the best of our knowledge, these features have not previously been explored. We also sought to characterize and determine, therefore, the differences in technique and outcome according to whether the stenotic lesions were positioned proximally or distally within the pulmonary arterial tree.

Methods

Selection of cases

The institutional review board of Children's Hospital of Boston approved our retrospective review of computerized databases, medical records, and angiographic studies. From the Departmental databases, we identified all catheterization procedures with codes indicating performance of pulmonary arterial angioplasty between January 1, 1996, and December 31, 2000. This period was chosen to include the period after the introduction of the most recent generation of high pressure balloons, but before introduction of the Cutting Balloon. We randomly selected 141 procedures from the original data set of 711 reports. We then eliminated 3 of these cases due to insufficient angiographic data, and 34 cases done for primary placement of a stent, defined either as no balloon dilation prior to delivery of the stent, or inflation of a balloon smaller than the balloon used to deliver the stent, or redilation of the stent. The determination of the size of the sample assumed a rate of restenosis at follow-up catheterization as 15%, within 95% confidence intervals of plus or minus 6%, with follow-up data available from 64% of patients initially dilated, and approximately 2 vessels dilated per procedure.

Data specific to the vessels

Review of medical records, catheterization reports, and angiograms determined if a vessel had been exposed to prior dilations or surgery, including arterioplasty, unifocalization, or anastomosis to a conduit. As angiographic review of these data proceeded, evidence suggested a substantial difference between proximal lesions within the right and left pulmonary arteries, and distal lesions located within the intraparenchymal arteries at lobar and sub-lobar levels, in terms of technique, results, and adverse events. Consequently, we categorised all vessels as proximal or distal, and incorporated that classification into all data collection and analysis.

Record of adverse events

We categorized all events as minor or serious, with minor events resulting in some transient impairment of a body function, or successful interventions that prevented permanent impairment of body function or restored flow following vascular trauma. Serious events were life-threatening, required major intervention such as surgery, or resulted in permanent bodily injury despite interventions.

Data analysis

Differences in the characteristics of either the patients or the procedures according to the location of the stenotic lesions were evaluated using the Kruskal-Wallis test for continuous variables, and Fisher's exact test for categorical variables. Thus, we used Fisher's exact test to assess differences in the characteristics of the vessels and angioplasty according to their proximal or distal location. Changes in the minimal luminal diameter were evaluated using the paired t test, and were compared for proximal and distal vessels using the two-sample t test. We generated 95% confidence intervals for serious adverse events and rates of restenosis using the exact binomial method.

Results

Patients and catheterization procedures

We evaluated 104 procedures involving angioplasty of 203 vessels. Table 1 summarizes the characteristics of the patients and procedures according to the site of angioplasty. In the 100 patients treated, obstructions occurred proximally in 53, distally in 37, and both in 10. Patients with common arterial trunk, or other diagnoses including functionally single ventricle, commonly received only proximal angioplasty (p smaller than 0.001). In the group undergoing only proximal dilations, procedures were performed at a younger median age, of 4 years for proximal lesions, 10 years for distal lesions, and 8 years for patients with proximal and distal lesions (p equal to 0.006). Characteristics of procedures performed for distal dilations included longer length of procedure, more fluoroscopic time, and dilation of more than one vessel.

Most catheterization procedures relied on conscious sedation. Given the serious nature of the underlying cardiac diseases, nonetheless, general anesthesia was begun at the start of 9 procedures, and added during the case in an additional 7 procedures. It is our institutional bias to consider transfusion of red cells electively when intra-procedural haematocrits are less than 35%, resulting in transfusion at 30% of the procedures. Following the procedure, 23 patients received care in the intensive care unit. There were

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Table 1. Characteristics of patients and catheterization procedure according to site of dilation.

	Proximal	Distal	Both	p value
Patients	*n = 53*	*n = 37*	*n = 10*	
Median age (year)	4	10	8	0.006
Diagnosis				
TOF	24 (45%)	13 (35%)	9 (90%)	<0.001
Common arterial trunk	10 (19%)	2 (5%)	0	
PPS	2 (4%)	14 (38%)	0	
Thromboembolic	0	5 (14%)	0	
Other	17 (32%)	3 (8%)	1 (10%)	
Anatomic shunt present	22 (42%)	15 (41%)	4 (40%)	ns
Catheterization procedures	*n = 55*	*n = 39*	*n = 10*	
Median procedure time (hours)	2.5	3.0	3.5	0.04
Median fluoroscopy time (minutes)	53	79	83	<0.001
Median # of vessels treated (range)	1 (1 to 2)	2 (1 to 11)	2 (2 to 4)	<0.001
Adverse event requiring intervention	14 (25%)	12 (31%)	2 (20%)	ns

Table 2. Characteristics of vessels and angioplasty procedures according to site of dilation.

	Proximal (n = 78)	Distal (n = 125)	p value
History of surgery at site*	68 (87%)	24 (19%)	<0.001
Balloon burst pressure >10 ATM	35 (45%)	108 (86%)	<0.001
Waist eliminated with first balloon	61 (78%)	7 (63%)	0.03
Waist eliminated with second balloon	34/43 (79%)	33/59 (56%)	0.02
Stent for recoil	19 (24%)	2 (2%)	<0.001
Stent for trauma	6 (8%)	4 (3%)	ns

*Conduit insertion, shunt insertion, pulmonary arterial patch augmentation

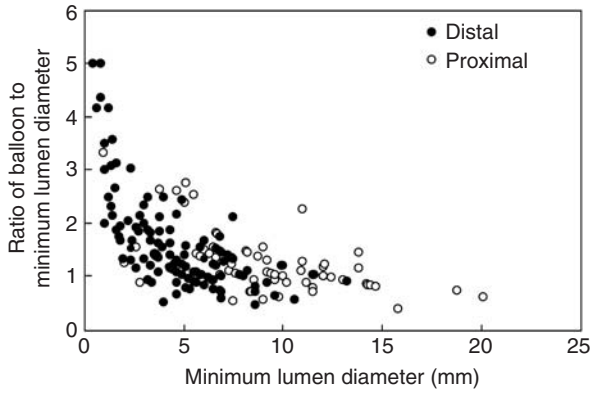

Figure 1.
Ratio of the size of the balloon size to the maximal luminal diameter plotted against the maximal luminal diameter.

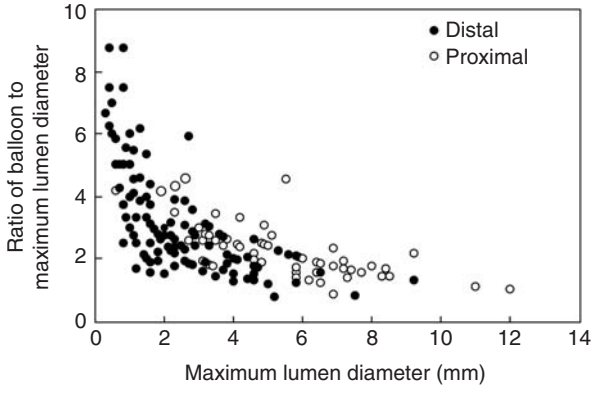

Figure 2.
Ratio of the size of the balloon size to the minimal luminal diameter plotted against the minimal luminal diameter.

no significant differences in rates of transfusion, anesthetic management, or need for intensive care for patients with proximal as opposed to distal lesions. We considered a change in systemic saturation of oxygen in patients with a shunt, and change in right ventricular pressure in patients without a shunt, as potential clinical surrogates for efficacy, but found no statistically significant difference after the procedure in either those with proximal or distal lesions.

Vessels and angioplasty procedures

Table 2 summarizes differences in the vessels and angioplasty procedures according to the site of dilation. Proximal dilations frequently involved a prior surgical site, including anastomoses with a conduit, surgical arterioplasty, or insertion of a shunt. These sites appeared more compliant and amenable to conventional angioplasty, as evidenced by more common elimination of the waist when dilating proximal sites. For more resistant distal sites of dilation, we were more likely to have chosen balloons capable of inflation at high pressure. In addition to these findings, the size of the balloon relative to the vessel differed, with larger ratios of the balloon to the minimal luminal diameter being found for distal dilations, at 2.7 versus 2.0

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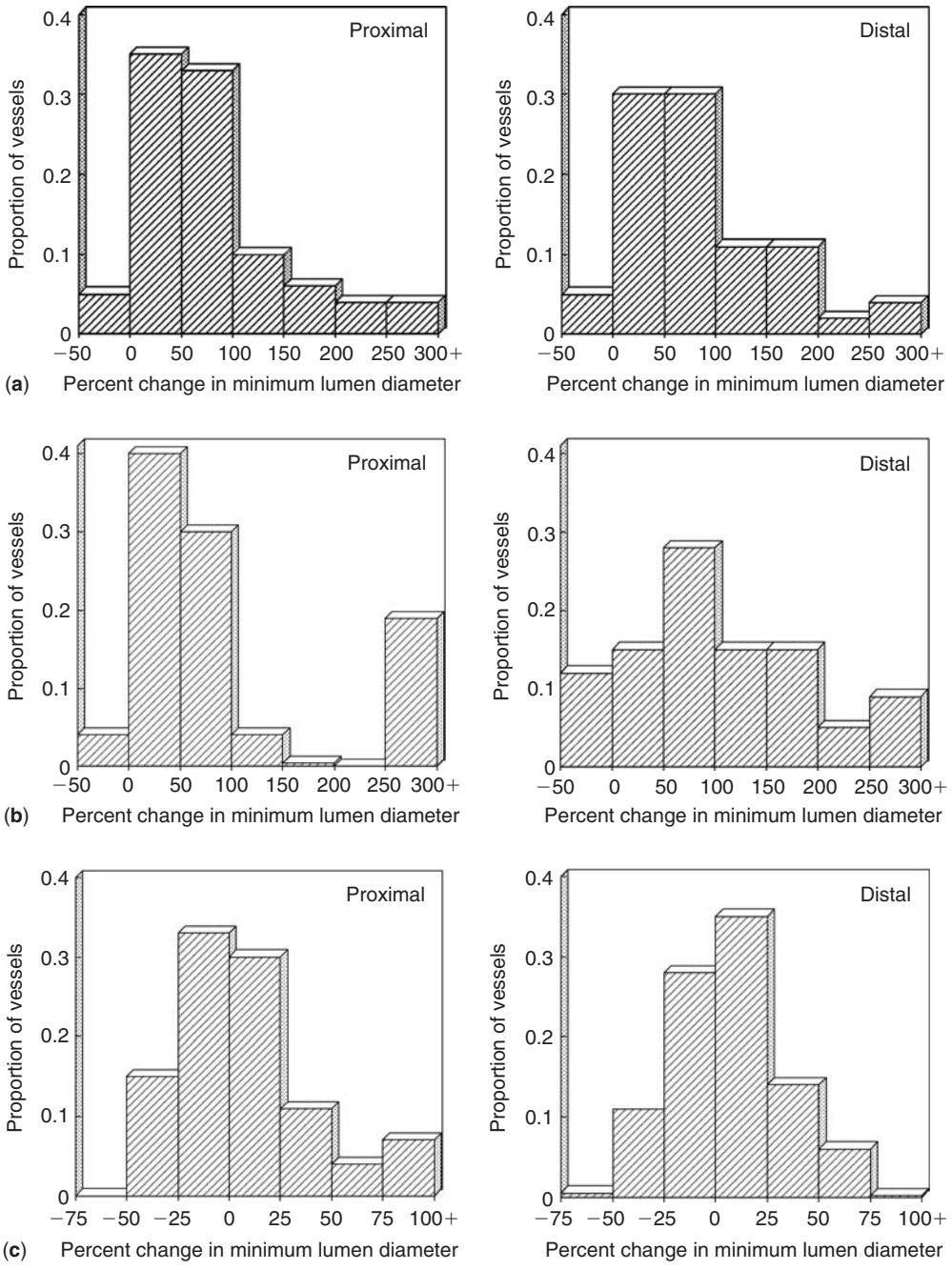

Figure 3.
*Proportional changes in luminal diameter: (**a**) initial to final measurement, (**b**) initial to follow-up measurement, and (**c**) final to follow-up measurement.*

(p smaller than 0.001) for the first balloon, and 2.9 versus 2.6 (p equal to 0.09) for the second balloon. The ratios of the balloon to the minimal and maximal luminal diameter plotted against the diameter of the vessels are shown in Figures 1 and 2.

Changes in luminal diameter

The mean minimal luminal diameter for the 203 vessels increased from 3.3 plus or minus 2.3 to 5.5 plus or minus 3.3 millimetres (p smaller than 0.001), representing an increase of 90 plus or minus 78% compared to the minimal luminal diameter measured at the initial procedure. The distribution of proportional increase in luminal diameter for the individual vessels according to the site of dilation is shown in Figure 3a. The mean luminal diameter increased from 2.3 plus or minus 1.6 to 3.8 plus or minus 2.1 millimetres in 119 distal vessels, and from 4.9 plus or minus 2.4 to 7.1 plus or minus 2.7

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Table 3. Angiographic appearance of vessels following angioplasty.

	Proximal (n = 78)	Distal (n = 125)	p value
Luminal appearance			ns
Smooth appearance	54 (69%)	75 (60%)	
Minimal filling defect no obstruction	19 (24%)	42 (34%)	
Significant filling defect with obstruction	5 (6%)	8 (6%)	
Contrast extravasation			ns
None	69 (89%)	111 (89%)	
Minimal within 2 mm of vessel	5 (6%)	9 (7%)	
Confined tear	4 (5%)	3 (2%)	
Unconfined tear	0	2 (2%)	
Aneurysm detected	3 (4%)	4 (3%)	ns

Table 4. Adverse events.

Dilation site at procedure	Proximal (n = 55)	Distal (n = 39)	Both (n = 10)
Serious			
Vessel tear treated with coil occlusion	0	2	0
Cardiac arrest	1	0	0
Total	1	2	0
Minor			
Arrhythmia	2	2	1
Haemodynamic instability	1	2	0
Stent for vessel trauma	6	3	1
Coil embolization requiring retrieval	1	0	0
Pulmonary oedema	3	3	0
Respiratory acidosis	1	1	0
Total	14	11	2

millimetres for 53 proximal vessels (p smaller than 0.001). Stents were placed in 31 vessels. The results of angioplasty in the remaining vessels revealed a greater proportional gain in luminal diameter for distal as opposed to proximal vessels, at 90 plus or minus 77% versus 64 plus or minus 70%, p equal to 0.002.

Following angioplasty, we found it necessary to insert stents either because the angioplasty had failed because of recoil, or for management of vascular trauma. Of the 31 stented vessels, 20 showed no evidence of trauma and had undergone only a minimal change in luminal diameter, namely 42% plus or minus 48%, following simple balloon angioplasty. These characteristics were found in 19 of 78 proximal dilations, as opposed to 2 of 125 distal dilations, p equal to 0.001. Stents were placed more frequently distally so as to manage vascular trauma, in 4 of 5 cases, as opposed to 6 of 25 proximal sites (p equal to 0.07). Regardless of indication or site, stented vessels had greater gains in luminal diameter for both distal and proximal sites, 163 plus or minus 91% for distal stents, and 126 plus or minus 71% for proximal stents (p equal to 0.001).

Angiographic evidence of trauma

Table 3 summarizes the angiographic appearance of the vessels. There were no statistically significant differences between proximal and distal vessels according to angiographic appearance, tears, or aneurysms.

Adverse events

Serious adverse events occurred in 3 of 104 procedures. In 2 distal vessels, unconfined tears necessitated occlusion using coils. Cardiac arrest occurred in one patient when a stent embolized to the pulmonary trunk. The patient was successfully resuscitated in the catheterization laboratory, and the stent was removed. We did not find a statistical difference in rates of serious adverse events according to the sites of dilation, albeit that the analysis is limited by the infrequent number of events.

The types of adverse event, designated seriousness, and attributability are shown in Table 4. We encountered 27 minor events in 25 patients. Of these, 6 patients received diuretics or continued mechanical ventilation for pulmonary oedema. We treated tachyarrhythmias in 5 patients with medication, overdrive pacing, or electrical cardioversion. Documented haemodynamic instability resulting in hypotension or metabolic acidosis occurred in 3 patients. Mechanical ventilation for respiratory depression and obstruction of the airway was needed in 2 patients, and an embolized coil was retrieved in 1 patient. Treatment for vascular trauma, consisting in placement of a stent, was needed in 10 patients. No deaths or emergent surgeries occurred.

Follow-up angiography

Of the 104 procedures, a subsequent catheterization followed the first procedure in 42 cases at a median of 11 months, with a range from 7 days to 76 months. We were able to review findings from 92 previously dilated vessels, more often following distal dilation. As is shown in Figure 3b, both proximal and distal vessels remained larger than their diameter prior to angioplasty, by 112 plus or minus 117% in 61 distal vessels, and 106 plus or minus 137% in 20 proximal vessels (p less than 0.001). The proportional loss of lumen between the two procedures is shown in Figure 3c. The mean loss in luminal diameter of the stents from final to follow-up was 0.5 plus or minus 1.3 millimetres for the 7 proximal vessels, and 0.1

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plus or minus 0.9 millimetres for the 4 distal vessels. Restenosis occurred in 9 vessels (10%), defined as a return to the diameter prior to dilation. There was no statistically significant difference in the rate of restenosis for proximal as opposed to distal lesions (p equal to 0.27).

Identification and characterization of tears as described in Table 3 allowed us to evaluate differences in restenosis, as well as changes in luminal diameter at follow-up, according to the angiographic appearance of the vessel. The occurrence of a non-obstructive filling defect did not predict loss in luminal diameter at follow-up. Follow-up was available in 3 of 7 aneurysmal vessels. The aneurysm persisted with no change in 2, and resolved in one. In all cases with follow-up data, angiography revealed no evidence of previously unrecognized trauma or aneurysms.

Discussion

Pulmonary arterial angioplasty has now been performed over a period of 20 years, with an evolution of technology resulting in low-profile, easy tracking, and non-compliant balloons. Our examination of 104 cases was specifically designed to provide a "modern" understanding of the outcomes and risk that can be expected with this procedure. The cases, randomly chosen from a much larger sample, and excluding patients with insufficient data and those undergoing primary stenting, provided representative estimates of rates of early improvement in luminal diameter, restenosis, and serious complications. We discovered that these questions are best answered by separating those dilations performed at proximal and distal sites.

Acute efficacy and technical considerations

In previous work,[1,3,6] successful angioplasty has been arbitrarily defined as an increase in the diameter over that seen prior to dilation of more than half, by an increase in lung perfusion, or by decrease in the ratio of right ventricular to aortic pressures. These criterions may be misleading for both large and small vessels. Temporary occlusion of large vessels may produce reflexive systemic vasoconstriction, and an undeserved fall in the ratio of right ventricular to aortic pressure. Successful dilation of rather small sublobar arteries, on the other hand, may have minimal acute gross physiologic impact. Others have detected clinically significant improvements by lungs scan or echocardiogram following purportedly unsuccessful dilations.[6,7] In our study, relying on changes in angiographic diameter, we have shown that lesions positioned proximally as opposed to distally respond very differently to standard balloon angioplasty.

We believe that our study, which documents the most recent results of simple angioplasty, and demonstrates the important differences between distal and proximal lesions, is particularly timely for several reasons. Firstly, regulatory agencies in the United States of America, Europe, and Japan are increasingly requiring sophisticated analyses of outcome before approving new devices and techniques, even in cardiac disease as seen in children. Secondly, some workers contend that the characteristics of recoil make implantation of stents the treatment of choice for all, or nearly all, pulmonary arterial obstructions, a contention that can only be tested against the results of modern angioplasty. Third, any valid assessment of new techniques, such as use of cutting balloons or new stent technologies, should utilize contemporary data and, perhaps, be separated into procedures for proximal as opposed to distal lesions.

Despite improvements in conventional balloon angioplasty, with luminal diameters increased by 90% distally, and 65% proximally, approximately one-third of vessels remain resistant to angioplasty, as evidenced by a persistent waist. These data suggest minimal impact on resistant stenosis since the introduction of high-pressure balloons 10 years ago.[6] In this report, we have characterized the response to dilation by the site of the obstructions. Proximal obstructions frequently occur at sites of previous surgery, and appear to be more compliant, with the waist eliminated more frequently during the first and second inflations of the balloon when compared to more resistant distal sites. In addition to these characteristics, proximal vessels are more likely to experience recoil, and hence need placement of stents so as to make adequate gains in luminal diameter. Based on these data, we opine that the mechanisms for obstruction are probably different for proximal as opposed to distal lesions.

The size of the balloon chosen for angioplasty has been found to be an important predictor of a successful increase in luminal diameter. Early in the transcatheter angioplasty experience, Kan et al.[4] reported greater increases in diameter for vessels having a ratio of balloon to diameter greater than 3.0. Subsequently, over the same period of time, Rothman et al.[3] reported rates of success of 73%, compared to 45%, for ratios greater than 3.5. Success, nonetheless, seemed to be related to resolution of the waist in a balloon, as explored by Gentles et al.[6] Such resolution was found in 57% of successful dilations, compared to 20% of failed procedures. In our series, we reviewed sequential dilations, and found that smaller ratios of balloon to diameter of vessel were chosen initially, and perhaps more importantly differed by position of the stenotic lesions, being 2.0

for proximal sites and 2.7 for distal sites. The ratios increased with subsequent dilations, documenting the increasing use of progressive angioplasty at our hospital. These differences highlight the necessary judgment the interventionalist must make when choosing the size of the balloon for angioplasty in pulmonary vessels of variable size.

Vessel trauma

We have characterized the angiographic appearance of trauma within the dilated vessels, and potential differences in late outcome in cases of minor trauma and therapeutic tears seen by angiography. Angiography after the procedure revealed some evidence of trauma in almost half of dilations, as characterized by intraluminal filling defects and/or extravasation. Most filling defects were non-obstructive, and did not require intervention, and similarly did not impact on acute changes in luminal diameter or predict loss of such luminal diameter at follow-up.

All significant vessel tears and trauma were effectively managed in the catheterization laboratory. In many cases, vessels with obstruction to distal flow were managed effectively with placement of stents. In contrast to proximal lesions, distal stents were more likely to be placed in response to vessel trauma. Similar to prior reports,[9] rupture occurred in only 1% of dilations. In our more recent experience, we have been able successfully to recognize and manage this event by coil embolization. More importantly, no new signs of trauma within the vessels were seen at late angiography.

Complications. Early in the clinical experience with pulmonary angioplasty, there was a relatively high risk of procedural mortality, at 3%, usually due to vascular trauma. Improvements in positioning the balloon,[3] and manufacture of balloons with lower profiles on more flexible catheters, has reduced mortality.[6] In the 1990s, our ability to recognize and treat catastrophic trauma by placement of stents and coil occlusion has further improved the safety of the procedure.[9] This trend towards better outcomes has continued in our recent experience. In our current experience, serious adverse events occurred in only 3 of 104. Of these events, two were attributable to angioplasty, both unconfined tears at distal sites of dilation managed by coil occlusion with no mortality. In general, although patients may experience arrhythmias, haemodynamic instability, or pulmonary oedema during these long and often technically challenging cases, the rate of serious adverse events is low.

Follow-up. As far as we know, ours is the largest series with follow up angiographic data after angioplasty, confirming lasting benefits following intervention. Of 92 vessels with follow-up data, one-tenth had returned to their diameters prior to dilation after sustaining gains at the initial procedure. This is consistent with rates reported in smaller series using a similar definition,[3,6,7] but less than the rate of 35% observed by Bush et al.[8] At follow-up, no significant differences in the proportional changes in luminal diameter from final to follow-up was found in proximal and distal stented and non-stented vessels, or in the extent of restenosis at distal as opposed to proximal sites. In addition, acute vascular injury characterized by non-obstructive intra-luminal damage or minimal extravasation did not adversely impact the late outcome of the initial gains in luminal diameter.

Limitations

The major limitation of our study is its retrospective design. Our adverse events were identified by a review of the catheterization reports. Although all known complications occur at the time of procedure, the true rate of adverse events, including late complications associated with the procedure, may not have been captured. In addition, incomplete data regarding the pressure of inflation of the balloons preclude reliable analysis of differences in efficacy or safety of angioplasty according to inflation at high or low pressures.

Summary

Pulmonary angioplasty has become a standard therapy for both proximal and distal pulmonary arterial stenosis. It is now one of the most common indications for catheterization in tertiary paediatric interventional laboratories. The initial inflation of the balloon may be critical for the evaluation of the compliance of the vessel, regardless of the site of dilation. In some cases it may prove therapeutic. Obstruction caused by compression, kinking, or in vessels with recoil characteristics, as evaluated by the first inflation, may require placement of a stent, more often in proximal vessels. Other vessels resistant to balloon angioplasty, by evidence of a persistent waist, may benefit from new technologies, such as dilation using Cutting Balloons. Serious adverse events were rare, and always found at the initial catheterization. Although both proximal and distal vessels may be resistant to simple angioplasty, this feature is much more common at distal sites. Our data captures the unique technical and outcome characteristics of pulmonary angioplasty at proximal and distal sites of obstruction, suggesting that trials designed to assess emerging technologies should analyze separately proximal as opposed to distal vessels.

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We thank JFK for his time, patience, wisdom and expertise.

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