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Anatomic and Technical Predictors of Stent Malposition During Implantation for Vascular Obstruction in Patients With Congenital and Acquired Heart Disease

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Objectives We evaluated the anatomic and technical factors predicting stent malposition and embolization in patients undergoing endovascular stent implantation for relief of noncoronary vascular obstruction.

Background Endovascular stent implantation provides a highly effective, minimally invasive solution to vascular obstruction in patients with structural heart disease. However, stent implantation is technically challenging and stent embolization occurs in up to 5.5% of cases.

Methods We reviewed patient and procedural characteristics of all endovascular stent implantations performed for relieving noncoronary vascular obstruction from January 1, 1999, through December 31, 2009. Univariate and multivariate predictors of stent malposition or embolization were explored through logistic regression methods.

Results During the 10-year study period, 429 stents were implanted. Of these, 399 were placed for relief of vascular obstruction in 267 patients during 322 procedures. Initial implantation failure occurred in 33 patients (8.3%), including stent malposition in 18 (4.5%) and stent embolization in 15 (3.8%). Patient size and vascular obstruction caused by external compression or a vascular fold were independent predictors of stent malposition or embolization. All malpositioned and embolized stents were successfully managed without surgery, and none resulted in death, sustained hemodynamic instability, or important vascular injury.

Conclusions Endovascular stent implantation is a highly effective and safe means of relieving noncoronary vascular obstruction in patients with congenital and acquired structural heart disease. Stent embolization occurs in approximately 3.8% of implantation procedures but can be managed successfully without surgical intervention. Anatomic and technical factors predict stent malposition, and consideration of these factors may improve procedural results. (J Am Coll Cardiol Intv 2010;3: 1080–6) © 2010 by the American College of Cardiology Foundation

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Endovascular stent implantation has become a common means of relieving noncoronary vascular obstruction in children and adults with structural heart disease. The immediate hemodynamic effects of stent implantation are well documented (1–9). However, endovascular stent implantation is technically challenging and stent embolization complicates up to 5.5% of such procedures (1,2,5,6,10,11). The determinants of successful endovascular stent implantation, and the consequences of stent malposition are poorly studied. We sought to: 1) determine the technical and anatomic factors predicting stent malposition; and 2) describe the consequences of stent malposition and embolization in this patient population.

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Methods

Patients were identified from the University of California, San Francisco Pediatric Cardiac Catheterization Laboratory database through a computerized search for all procedures involving the placement of a balloon-expandable endovascular stent during the period of January 1, 1999, through December 31, 2009. Self-expanding and intraoperative stent placements were not included. All cardiac catheterization reports and angiographic images were reviewed. Data on predictor variables were abstracted by the primary investigator prior to ascertainment of the outcome. Patients were excluded from analysis if stent placement was not for the purpose of vascular obstruction (e.g., patent ductus arteriosus, atrial or ventricular septal stenting). Right ventricle–to–pulmonary artery conduits and aortopulmonary shunts were included.

Definition of outcome variables. The outcome of stent placement was recorded as a pre-specified ordinal variable as perfect, adequate, malposition, or embolized. Both *perfect* and *adequate* stent placement were considered *implantation success* and required successful placement of the stent across the area of vascular obstruction with greater than 50% decrease in measured pressure gradient and/or final expansion of the stenotic lesion to at least 75% of the diameter of the balloon used to implant the stent. Perfect and adequate stent placement differed qualitatively based upon final positioning relative to the surrounding anatomic structures to account for complex anatomic settings, such as bifurcation lesions. For example, precise "centering" of the stent upon the lesion was not considered criteria for a perfect implantation if the anatomy suggested that alternative position was necessary to achieve an optimal anatomic or hemodynamic result. Similarly, avoidable jailing of a side branch vessel during an otherwise perfect implantation resulted in classification as *adequate* rather than *perfect*. Classification as an *implantation failure* included both stent *malposition* and stent *embolization*. Categorization as *stent malposition* required stable placement of the stent in the area of vascular obstruction but with an inadequate hemodynamic or angiographic result such that additional stent placement or intervention was required. Simple redilation of a successfully placed stent and intentional placement of multiple stents were not considered criteria for stent malposition. A stent was considered *embolized* if it was not adherent to the vascular wall and was mobile in the circulation at any point after balloon inflation. In an effort to provide the most clinically useful analysis based upon the need for further intervention, final analysis was based upon dichotomous classification of the outcome variable as implantation success (perfect and adequate) or implantation failure (malposition and embolization).

Definitions of predictor variables. *Balloon-stenosis ratio* was defined as the unitless ratio of delivery balloon diameter to the minimal lumen diameter of the vascular obstruction. *Balloon-stent ratio* was defined as the unitless ratio of the balloon length to unexpanded stent length. *Pre-dilation* was defined as full inflation of an angioplasty balloon across the vascular lesion prior to implantation of the stent. Partial inflation of an angioplasty balloon across the lesion was not considered pre-dilation. Vascular lesions were classified into 1 of 4 categories based upon the angiographic appearance prior to intervention (Fig. 1). *Discrete obstruction* was defined as focal narrowing of the vascular lumen (Fig. 1A). *Diffuse obstruction* was defined as a long-segment narrowing or hypoplasia of the vascular lumen without external compression (Fig. 1B). Vascular folds and external compression were defined by the relationship of the obstructed vessel with itself or surrounding structures, respectively (Fig. 1C). For analysis, these last 2 lesions were considered together as highly compliant lesions. The final category of vascular lesion was any type of vascular obstruction already containing an endovascular stent (Fig. 1D). This category was created to reflect the combined effects of a relatively predictable noncompliant "landing zone" and continuous visual landmark during stent implantation.

Abbreviations and Acronyms

CI = confidence interval

OR = odds ratio

Data analysis. Data were collected into a standard spreadsheet (Microsoft Excel, Microsoft, Redmond, Washington) and exported to STATA version 11 (StataCorp, College Station, Texas) for statistical analysis. Normally distributed continuous variables were summarized as means and standard deviations. Non-normally distributed variables were summarized as medians and ranges. Comparison of pre- and post-procedural paired data was performed using the paired samples *t* test or Wilcoxon signed ranks test, as appropriate to their distributions. Evaluation of unadjusted risk factors for stent implantation failure was performed using logistic regression with clustering on patient study identification number. Adjusted analysis of risk factors for

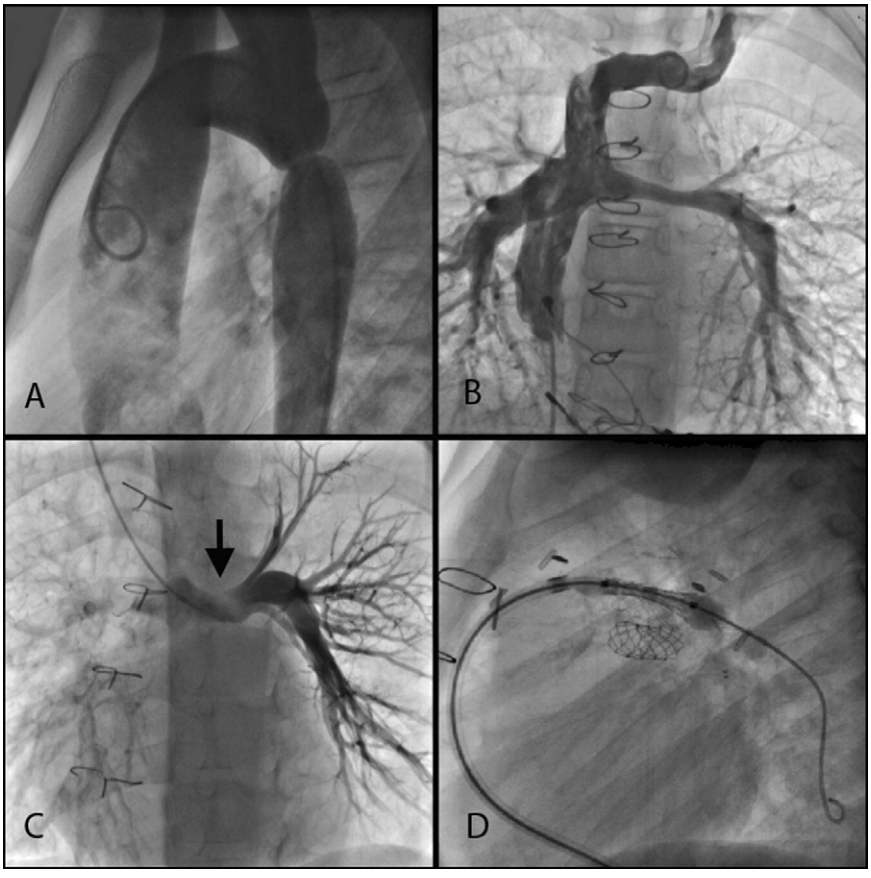

Figure 1. Classification of Vascular Obstruction

(A) *Discrete* obstruction in a patient with coarctation of the aorta. **(B)** *Hypoplasia* of the left pulmonary artery in a patient after Fontan (compression was excluded by additional angiography). **(C)** *Compression* of the left pulmonary artery by the ascending thoracic aorta in a patient after superior cavopulmonary connection (note contrast translucency at area of compression **(arrow)**, an overlying aortic position was demonstrated in a separate angiogram). **(D)** Vascular obstruction at site of fractured *existing stent* in left pulmonary artery.

stent implantation failure was performed using multiple variable logistic regression with clustering on patient study identification number. Final model selection was performed using backward selection with maximization of the area under the receiver-operator characteristic curve and minimization of the Akaike and Bayesian information criteria. Standard model checking was performed.

Results

Patient, anatomic, and procedural characteristics. During the 10-year study period, 429 stents were implanted. Of these, 399 were placed for relief of vascular obstruction in 267 patients during 322 procedures (Table 1). The remaining 30 stents were placed for reasons other than vascular obstruction. Seventy-six subjects had more than 1 stent implanted (range 2 to 6). The total number of stents implanted per year varied moderately, ranging from 31 to 55; however, most variation was explained by case volume as the proportion of cases involving stent implantation remained fairly constant (6.9% to 8.5%). Most stents were placed in either the aorta or pulmonary arteries.

The median patient age at the time of stent implantation was 9 years (ranging from 2 days to 59 years). Endovascular stent placement in infants and smaller children occurred most frequently in the setting of emergent perioperative hemodynamic instability, in non-native sources of pulmonary blood flow (shunts or conduits), or as palliative interventions in patients deemed unsuitable for surgery.

Endovascular stent placement resulted in significant reductions in measured pressure gradients (Table 2). In pulsatile circulations, the median percent reduction in peak systolic pressure gradients was 85% (10% to 100%). Ten procedures had residual peak gradients >20 mm Hg, of which 3 were intentionally staged interventions with subsequent hemodynamic success upon reintervention.

Table 1. Patient and Vascular Characteristics

Stents	399	
Patients	267	
Procedures	322	
Median patient age, yrs	9	2 days–58 years
Median body surface area, m^2	1.14	0.16–2.37
Patient diagnosis		
Tetralogy of Fallot	110	
Isolated coarctation	104	
Single ventricle	71	
Other	101	
Type of stent		
Bare metal	370	93%
Pre-mounted	136	34%
Drug eluting	14	3.5%
Covered	10	2.5%
Site of stent placement		
Aorta	131	33%
Pulmonary artery	200	50%
Main pulmonary artery	3	
Proximal left pulmonary artery	108	
Proximal right pulmonary artery	56	
Branch left pulmonary artery	12	
Branch right pulmonary artery	20	
Systemic/pulmonary vein	27	7%
Superior vena cava	12	
Inferior vena cava	2	
Pulmonary vein	11	
Other systemic vein	2	
Right ventricular outflow tract or RV-PA conduit	21	5%
Fontan conduit/pathway	9	2%
Aortopulmonary shunt	8	2%
Aortopulmonary collateral	3	1%

RV-PA = right ventricular-pulmonary artery.

Stent malposition and embolization. Stent malposition or embolization occurred in 33 (8%) of 399 stent implantations (Table 3). Fifteen stents (3.8%) embolized during implantation in 13 patients. The 18 remaining malpositioned stents were stable within the intended vascular structure but failed to yield either acceptable anatomic or hemodynamic results. In all of these cases, additional stent placement resulted in procedural success. There were 16 pairs of bifurcating or "kissing" stents. None resulted in malposition or embolization. Balloon rupture during stent implantation occurred in 16 cases but directly contributed to stent malposition in only 4 (embolization in 2). The odds ratio (OR) for stent malposition with balloon rupture during implantation was 3.7 (95% confidence interval [CI]: 1.20 to 11.62). Stent malposition that occurred as a result of balloon rupture was excluded from further risk factor analysis.

Table 2. Median (Range) of Initial and Final Pressure Gradients

Site	Initial Gradient	Final Gradient	p Value
Pulsatile circulations	25 (3–120)	5 (1–56)	<0.0001
Aorta	25 (4–85)	1 (1–45)	<0.0001
Pulmonary artery	22 (3–120)	7.5 (1–41)	<0.0001
Nonpulsatile circulations	6.9 (1–21)	2.4 (1–3.9)	<0.0001

Table 3. Outcome of Stent Placement

Implantation success	366	91.7%
Perfect	205	51.4%
Adequate	161	40.3%
Implantation failure	33	8.3%
Malposition	18	4.5%
Embolization	15	3.8%

Univariate predictors of stent malposition or embolization included pre-dilation of the vascular obstruction (OR: 2.5, 95% CI: 1.13 to 5.53) and obstruction due to vascular fold or external compression (OR: 20.6, 95% CI: 6.78 to 62.40) (Table 4). There was no influence of date of implantation upon risk for malposition or embolization. Independent predictors of stent malposition or embolization included body surface area (OR: 2.5, 95% CI: 1.15 to 5.42) and vascular obstruction due to fold or external compression (OR: 20.2, 95% CI: 5.64 to 72.03) (Table 5). After adjustment, the odds ratio associated with pre-dilation remained relatively consistent, at 2.37, with borderline statistical significance, $p = 0.07$.

Outcome of embolized stents. Of the 15 stents that became unstable in circulation, 2 were repositioned and secured within the intended location with a larger balloon, 5 were repositioned in the intended location and secured with the placement of an additional stent, and 7 were placed in an unintended vascular structures (contralateral pulmonary artery in 3, descending thoracic aorta in 3, and iliac artery in 1). One stent was compressed with the use of multiple snares and removed from the body through a long sheath.

Table 4. Unadjusted Risk Factors for Stent Malposition and Embolization

	OR	p Value	95% CI
Age, yrs	0.99	0.87	0.97–1.03
Body surface area, m^2	1.02	0.89	0.78–1.30
Pre-dilation	2.51	0.02	1.13–5.53
Pre-mounted stent	1.19	0.67	0.53–2.67
Stent length, mm	0.99	0.51	0.95–1.03
Balloon-stent ratio	1.76	0.20	0.73–4.22
Stenosis-balloon ratio	0.97	0.62	0.86–1.09
Pulsatile circulation	1.85	0.30	0.58–5.90
Type of vascular obstruction			
Discrete	Ref		
Hypoplastic	1.01	0.89	0.41–2.82
Fold/compression	20.60	<0.001	6.78–62.40
Existing stent	0.46	0.29	0.11–1.90

CI = confidence interval; OR = odds ratio; Ref = reference.

Table 5. Independent Risk Factors for Stent Malposition and Embolization

	OR	p Value	95% CI
Body surface area, m^2	2.50	0.02	1.15–5.42
Pre-dilation	2.37	0.07	0.94–5.97
Stent length, mm	0.95	0.12	0.89–1.01
Stenosis-balloon ratio	0.97	0.75	0.79–1.19
Type of vascular obstruction			
Discrete	Ref		
Hypoplastic	1.37	0.60	0.42–4.53
Fold/compression	20.20	<0.001	5.64–72.03
Existing stent	0.33	0.32	0.04–2.85

Abbreviations as in Table 4.

Table 7. Procedural Complications

Procedures	313	
Complications	47	15%
Major complications	11	3.5%
Aneurysm	4	
Uncontrolled tear	1	
Renal artery thrombosis	1	
Bronchial compression	1	
Stroke	2	
Hemoptysis	2	
Minor complications	37	11.8%
Balloon rupture	16	
Jailed vessel	17	
Other	10	

Stent embolization did not result in death, sustained hemodynamic instability, or serious vascular injury in any case (upper limit of 95% CI: 22%).

Complications. Median procedure time, fluoroscopy time, and contrast use were higher in cases involving stent malposition or embolization (Table 6); however, only the difference in fluoroscopy time was statistically significant. Complications other than stent malposition or embolization occurred in 47 of 322 procedures (Table 7). The majority of complications were minor. Eleven major complications occurred, including 1 death from an uncontained aortic tear. No major complication occurred as a result of stent malposition or embolization.

Discussion

Noncoronary vascular obstruction occurs commonly in many forms of congenital and acquired structural heart disease and is an important cause of morbidity and mortality. Conventional therapeutic interventions in this situation are surgery, balloon angioplasty, or endovascular stent implantation. Among the available options, endovascular stent implantation provides a highly effective, minimally invasive solution to vascular obstruction, with relatively low risk, procedural cost, and hospital lengths of stay (1,2,6,12–15). Because of concern for long-term vascular growth, stent implantation has been traditionally reserved for adults and larger children. However, with the recognition that stents can be further expanded and even broken through additional dilation to keep up with somatic growth (16,17), the population of patients undergoing stent placement has expanded. However, stent implantation remains technically challenging. Despite refinements in equipment and technique, stent embolization occurs in 1.2% to 5.5% of stent implantation procedures, and approximately one-half of these appear to require surgical intervention (1,2,5,6,10,11). Information regarding stent malposition without frank embolization is absent from the literature and may be underreported because subsequent stent placement frequently results in a hemodynamically and technically successful procedure.

Table 6. Median (Range) of Procedure Time, Fluoroscopy Time, and Contrast Use

	Implantation Failure	Implantation Success	p Value
Procedure time, min	334.6 (160–600)	303.4 (95–735)	0.13
Fluoroscopy time, min	67.3 (21.9–147.5)	52.8 (7.3–183)	0.04
Contrast, cc/kg	2.4 (0.8–8.7)	2.3 (0.8–8.7)	0.14

This study was undertaken with the conceptual framework that the determinants of successful endovascular stent placement may be broadly classified under 3 categories. The first encompasses characteristics of the patient and vascular lesion; including patient size, the type of vascular obstruction, and the size and type of the obstructed vessel. The second encompasses equipment and technical factors, such as stent size or type, or factors that arise as a result of the interface of these with the vascular lesion, such as the relation of the stent or balloon to the vascular segment. The final category is operator proficiency.

Patient and vascular determinants. We examined the roles of patient and vessel size and type of vascular obstruction upon stent placement and found the type of vascular obstruction to be the strongest predictor of stent implantation failure. Relative to discrete vascular obstructions, vascular obstruction due to vascular fold or external compression was associated with a 20-fold increase in the odds of stent malposition or embolization. These are relatively uncommon causes of vascular obstruction, comprising only 4% of this series, but may be underappreciated. External compression may be missed if not specifically considered and investigated, and the angiographic appearance of vascular folds may be mistaken for discrete stenosis if not carefully examined. Unfortunately, the associated risk of these lesions for stent implantation failure may be difficult to manage because it is precisely these types of vascular obstruction that are unlikely to respond to balloon angioplasty without stent implantation. Pre-dilation of a lesion

may provide insight into its compliance and thereby help distinguish discrete obstruction from vascular folds, but pre-dilation may carry independent risks. It seems reasonable that the use of larger implantation balloon diameters might mitigate this risk by providing better radial force against these highly compliant vascular lesions but we are unable to support this hypothesis with the available data.

We also found an association between larger patient size and the risk for failure. Interventional procedures in small children are often considered technically more challenging. With respect to stent implantation, however, the greater vascular space of larger patients may permit more room for undesired balloon movement during stent implantation. We found no association between stent malposition or embolization and patient age or implantation in a pulsatile circulation when controlled for other factors.

Equipment and technical determinants. We also examined the roles of several technical factors upon stent placement, including the use of pre-mounted stents, pre-dilation of the vascular lesion, stent length, the ratio of stent length to balloon length, and the ratio of delivery balloon diameter to minimal lumen diameter. Among these, only pre-dilation of the vascular lesion was associated with an increased odds of imprecise stent placement, although with only borderline statistical significance. The relationship is plausible because pre-dilation may reduce the effective vascular scaffold upon which the stent must be secured. However, caution should be exercised in consideration of this finding: not only because of the borderline test statistic, but also because residual confounding may exist. Specifically, the indications for pre-dilation were neither standardized nor routinely recorded. It is likely that pre-dilation was performed more commonly in technically challenging lesions in order to assess balloon stability prior to stent implantation. This institutional bias as well as other important considerations, such as partial pre-dilation, are not accounted for in our model and may confound the association between pre-dilation and subsequent stent placement.

The consequences of stent malposition and embolization. All procedures with poorly positioned but stable (malpositioned) stents were ultimately successful with additional intervention during the same procedure. No stent embolization in this series required surgical intervention and all procedures involving stent embolization were ultimately successful during the same procedure after additional intervention.

Study limitations. We were unable to assess the important effect of the primary interventionalist upon stent implantation for several reasons. First, at this institution, complex interventional cases are often performed with the assistance of more than 1 attending interventionalist. As a result, because of the retrospective nature of this study, we were unable to identify and analyze the roles of specific individuals. In addition, the majority of stent implantations over the study period were performed by a single interventionalist, to whom a clear case complexity bias existed that was difficult to quantify. Finally, despite consideration of multiple variables in this analysis residual confounding by unrecognized factors must remain a consideration.

Conclusions

Endovascular stent implantation is highly effective and a safe means of relieving noncoronary vascular obstruction in patients with congenital and acquired structural heart disease. Stent embolization occurs in approximately 3.8% of stent implantation procedures but may be managed successfully without surgical intervention. Anatomic and technical factors predict stent malposition and consideration of these factors may improve procedural results.

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