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Intraoperative Echocardiography for Congenital Aortic Valve Repair: Predictors of Early Reoperation

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Abstract

Background—We sought to identify post-cardiopulmonary bypass (CPB) transesophageal echocardiography (TEE) predictors of early reoperation for recurrent aortic regurgitation (AR) in patients undergoing repair for congenital aortic valve disease.

Methods—We analyzed post-CPB TEEs in patients with congenital aortic valve disease undergoing repair for predominant AR. Cases underwent reoperation for recurrent AR within 2 years whereas controls were free from reoperation for >3 years.

Results—Cases (n=22; median time to reoperation 0.3 years) and controls (n=22; median freedom from reoperation 4.4 years) were similar with respect to demographics, aortic dimensions, and preoperative AR grade. Among post-CPB TEE variables, univariate logistic regression analysis identified shorter coaptation height (OR for 1 mm increase 0.72, 95% CI 0.54–0.95, $p=0.02$), decreased ratio of coaptation height to annulus diameter (OR for a 5% decrease 1.37, 95% CI 1.06–1.77, $p=0.02$), and increased percent difference (%diff) between longest and shortest coaptation lengths in a short-axis view (OR for 10% increase 1.84, 95% CI 1.15–2.92, $p=0.01$) as risk factors for early reoperation for recurrent AR. Multivariable analysis identified %diff in short-axis coaptation lengths as the strongest post-CPB TEE predictor (area under receiver operator curve=.743). The sensitivity and specificity of a %diff of 50% were 0.45 and 0.91 whereas a %diff of 30% had a sensitivity of 0.75 and specificity of 0.67.

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Conclusions—Coaptation asymmetry, measured as increased %diff in short-axis coaptation lengths on post-CPB TEE, is associated with early reoperation for recurrent AR after congenital valve repair.

Keywords

Aortic valve; repair; CHD; valve; Echocardiography

INTRODUCTION

Aortic valve (AoV) repair is an attractive alternative to valve replacement for pediatric and congenital AoV disease [1–4]. While data have been encouraging regarding the durability of repair for adult patients with predominant aortic regurgitation (AR) [5–7], freedom from reoperation in the pediatric population is reduced [8, 9].

Although intraoperative post-cardiopulmonary bypass (CPB) transesophageal echocardiography (TEE) is routinely performed to evaluate the adequacy of AoV repair [10], findings associated with early recurrent AR have not been defined in the pediatric population. Predictors have been described in the adult population, primarily for patients with aortic root dilation or bicommissural AoV, and include shorter coaptation length and reduced coaptation height [11–13]. However, these may not be applicable in the pediatric population given the differences in underlying pathologies. Many pediatric patients have either had prior interventions for relief of aortic stenosis (AS), or have significant associated cardiac anomalies that impact the geometry of the left ventricular (LV) outflow and aortic root [14, 15]. Defining intraoperative markers of recurrent regurgitation leading to early reoperation may help identify candidates for intraoperative revision. We undertook an investigation to identify such markers.

PATIENTS AND METHODS

Patients

This was a retrospective single-center case-control study. The institutional review board of Boston Children's Hospital approved the investigation and waived the requirement for informed consent. The electronic database was queried for patients undergoing AoV surgery between January 2004 and May 2012. Cases underwent repair for moderate or greater AR with subsequent reoperation within 2 years for recurrent AR. Controls were free from reintervention on their AoV for at least 3 years. Subjects with severe AS were excluded.

Preoperative Variables

A single investigator (KS) blinded to case-control status reviewed all examinations. AoV Doppler gradients, LV size, and function were obtained from preoperative transthoracic echocardiography (TTE) reports. Measurements performed by the investigator on the preoperative TEE using Heartsuite VERICIS workstations (Emageon, Hartland, Wisconsin) included aortic annulus and root diameters in systole, vena contracta (VC) width of the AR jet from long-axis views, and cross-sectional area of the VC jet from short-axis views. If 2 AR jets were present, these were measured separately and summed. Data obtained from the

cardiac magnetic resonance (CMR) report included LV size and function and AR fraction. The reports from cardiac catheterizations were reviewed for AR grade and peak AoV gradient (post-intervention, if performed). AoV morphology, AR grade, and AS grade were determined by consensus of surgical description, imaging reports, and investigator review. AR severity was recorded according to recommendations of the American Society of Echocardiography [16]. AS severity was graded based on cardiac catheterization (when available) or continuous wave Doppler as none-to-trivial (peak gradient < 15 mm Hg), mild (15 to 35 mm Hg), moderate (36 to 70 mm Hg), or severe (>70 mm Hg).

Intraoperative Post-CPB TEE Variables

Width and area of the VC of AR jets were determined. Additional measurements are depicted in Figure 1. In systole, the percent opening of the aortic leaflet tips relative to the aortic annulus, an indicator of systolic leaflet restriction, was calculated. The lengths of the anterior and posterior leaflets relative to their respective aortic sinuses, a measurement of leaflet length adequacy, was recorded.

In diastole, the ratio of the heights of the tip and base of leaflet coaptation relative to the annulus diameter were calculated, as was the percent difference between the distances from leaflet coaptation tip to the anterior and posterior aortic walls (%diff-long), a measure of coaptation symmetry. From short-axis views, the coaptation lengths (distance from commissure to central coaptation point) and cusp areas were measured in diastole. For bicommissural valves, median raphe were measured, even if they were not patent, and conjoint cusps were measured as 2 separate cusps. To quantify coaptation symmetry, percent difference between longest and shortest coaptation lengths (%diff-short) during diastole was calculated as follows: %diff-short = [Difference between longest and shortest coaptation lengths/Average of longest and shortest coaptation lengths] x100 (Figure 2). Median raphe were measured because for %diff-short to truly represent coaptation symmetry, at least 3 coaptation lengths are required. The percent difference between the largest and smallest cusp areas was also calculated.

Postoperative and Follow-up Variables

First postoperative TTEs were reviewed for AoV gradients, VC of AR jets, and AR severity. For cases, mechanism of recurrent AR from surgical description was recorded, as were reoperation details. For controls, the latest available TTE was used as the follow-up examination. When available, follow-up CMR and catheterization data were also collected. A consensus AR and AS grade were determined.

Statistical Analysis

Continuous variables were summarized using the median and range, unless otherwise noted. Categorical variables were summarized as frequencies and percentages. Covariates were compared between cases and controls using Fisher's exact test for categorical variables and the unpaired t-test or the Wilcoxon rank-sum test for normally and non-normally distributed continuous variables, respectively. Univariate logistic regression analysis was performed for each variable to calculate odds ratios (OR) and 95% confidence intervals (CI) for early reoperation. For categorical variables with 1 or more levels experiencing low event rates for

cases or controls, Firth logistic regression was used to correct for potential bias in the OR and CI [17]. For variables with a p value < 0.20 in univariate analysis, a forward-selection model-building procedure was then performed to find the most parsimonious model for early reoperation for AR. A p value < 0.05 was considered statistically significant. Statistical analysis was performed using Stata version 12 (College Station, Texas).

RESULTS

Baseline Characteristics and Operative Variables

Of 310 potential subjects, 266 were excluded (Figure 3). The demographic and procedural data of the 22 cases and 22 controls are summarized in Table 1. Isolated congenital AoV disease was the most common diagnosis in both cases and controls. The degree of baseline AR was not significantly different between the 2 groups. Cases had a lower peak AoV Doppler gradient.

Aortic root and/or ascending aorta replacements were performed in 6 cases (27%) and 1 control (5%). Subaortic resections were performed in 4 controls (18%) and no cases ($p=0.05$ for both). There were no significant differences in repair technique, though a higher proportion of controls had leaflet augmentation or replacement procedures.

Intraoperative Post-CPB TEE

The degree of AR on the post-CPB TEE was mild or less in all subjects (Table 2). Compared with controls, cases had greater prolapse of the anterior leaflet below the annular plane, shorter coaptation height, shorter coaptation height relative to the annulus diameter, and a higher %diff-short.

Reoperation and Follow-up

For cases, the median time to reoperation was 0.3 years (range 3 days – 1.9 years). Median follow-up duration for controls was 4.4 years (range 3.1 – 8.1 years). Of the 22 cases, 7 (32%) underwent reoperation during the same hospitalization as the initial AoV repair.

The degree of AR on the first postoperative TTE was higher than on the post-CPB TEE for both cases and controls (Figure 4).

At the time of reoperation, one-half of the cases underwent repeat AoV repair while the remainder underwent AoV replacement. Of the mechanisms of recurrent regurgitation noted by intraoperative inspection, leaflet prolapse constituted 40%.

At the time of reoperation in cases, the AR grade was severe in 10 (45%), moderate in 10 (45%), and mild-moderate in 2 (10%). Both cases with mild-moderate AR underwent reoperation within 10 days of the initial repair as the regurgitation was judged to be progressive. At last follow-up of controls, AR grade was mild or less in 8 (36%), moderate in 12 (55%), and severe in 2 (9%). The degree of AS was not significantly different between groups, with 11 (50%) cases having none-to-trivial, 8 (36%) having mild, and 3 (14%) having moderate stenosis. Among controls, 14 (64%) had none-to-trivial, 7 (32%) had mild, and 1 (5%) had moderate AS.

Risk Factors for Early Reoperation for Recurrent AR

Among preoperative variables, a lower peak AS Doppler gradient on TTE was associated with early reoperation (Table 3). Among operative variables, leaflet augmentation and/or replacement was borderline protective. Performance of aortic root and/or ascending aorta replacement was associated with a significantly elevated risk of early reoperation while subaortic resection reduced the risk. Among intraoperative post-CPB TEE parameters, significant factors included shorter coaptation height, and lower ratio of coaptation height to annulus diameter. Patients with a greater %diff-short were at higher risk of early reoperation for recurrent AR (Figure 5).

A forward-selection model building procedure identified %diff-short as the strongest predictor among post-CPB TEE variables (OR for a 10% increase 1.84, 95% CI 1.15–2.92, $p=0.01$). The area under the receiver operator curve for %diff-short was 0.743. Using a cutpoint of 50%, the sensitivity and specificity of this model for predicting early reoperation were 0.45 and 0.91, respectively. An alternative cutpoint of 30% had a sensitivity of 0.75 and specificity of 0.67.

COMMENT

We found increased percent difference between the longest and shortest coaptation lengths in post-CPB TEE short-axis view, a marker of coaptation asymmetry, to be the strongest intraoperative echocardiographic predictor identifying patients at risk of early reoperation for recurrent AR.

Studies in adult patients have identified decreased coaptation height and cusp prolapse as markers of early valve failure [11–13]. These echocardiographic findings are consistent with the mechanism of recurrent AR observed on intraoperative inspection in our series, with 40% of cases having prolapse as a contributing factor. Despite the underlying differences in anatomy and associated cardiac defects between the adult and pediatric/congenital populations, leaflet prolapse and reduced coaptation height have emerged as common risk factors for recurrent AR.

Our findings add coaptation asymmetry as an important predictor of subsequent valve failure. A related measure, diastolic mobility of the aortic leaflets, has been described in patients undergoing congenital AoV repair for AR with cusp extension technique [18]. This was defined as the degree to which valve leaflets moved toward the center of the aortic root during diastole. While our measurement of %diff-short was not calculated the same way, the two measurements are likely related, and together provide support for the importance of symmetric leaflet coaptation at the center of the valve. Additionally, our observation that leaflet augmentation tended to be protective against early reoperation suggests that extensive reconstruction may be necessary to achieve coaptation symmetry.

The mechanism by which coaptation asymmetry increases the risk of AoV dysfunction is not entirely clear. Even in the normal AoV, there are asymmetric stress distributions [19]. It is reasonable to speculate that these stresses are exacerbated in pathologic states with increased asymmetry. Some in-vitro modeling has focused on increasing coaptation surfaces

in AR repair, which is achieved through larger leaflet replacements or augmentations [20]. Our findings provide further impetus to investigate coaptation asymmetry in computational models of leaflet stress.

In clinical practice, intraoperative echocardiographic markers of AoV dysfunction must be practical during post-CPB TEE. The parameter %diff-short appears to fulfill this requirement, as it is a simple calculation derived from a standard TEE view. The measurement is intuitively easy to understand as well, as the larger the difference between short-axis coaptation lengths, the more offset the center of leaflet coaptation will be (Figure 2). At present, calculations on 3-dimensional datasets or computational analysis of stress/strain relationships on valve leaflets are not yet available at the bedside in the operating room. However, such analytical tools deserve further investigation as they may offer more refined information.

We realize the difficulty in advising a return to bypass for revision of a repair in the absence of significant AR. Our findings, while statistically significant, lack a “clean” cut-off with both high sensitivity and specificity. However, using a %diff-short of 50%, specificity was high (0.91). This threshold is also relatively easy to compute, as it corresponds to a ratio of shortest-to-longest coaptation length of 6:10. Trading specificity for sensitivity, a cut point for %diff-short of 30% results in a sensitivity of 0.75; however, specificity decreases to 0.67.

Although not a focus of this investigation, we found a significant increase in risk of early reoperation for patients undergoing valve-sparing aortic root and/or ascending aorta replacement. It is not clear if this increased risk of reoperation is related to underlying patient characteristics such as connective tissue disease, or a result of manipulation of the aortic root with distortion of cusp geometry [12]. Investigations designed to address these questions in the pediatric population would be welcome.

Interestingly, we did not find a significant difference in degree of AR on post-CPB TEE between cases and controls (Table 2). This has been identified as a risk factor for earlier valve dysfunction [11]. The lower rate of significant AR on post-CPB TEE in our series and the modest sample size are potential contributors to this apparent discrepancy.

Limitations

The retrospective study design and small sample size are notable limitations of our study. It is possible that some of the parameters that did not reach statistical significance may be found to be important with a larger sample size. Furthermore, it is conceivable that with greater statistical power a more robust prediction model can be constructed. Additionally, although the baseline characteristics of the groups were comparable, several important differences existed, most notably a higher degree of AS in controls and a higher rate of surrogate markers for aortic root and/or ascending aorta enlargement in cases. Some of these limitations can be overcome with a multicenter prospective study.

In conclusion, %diff-short, a marker of AoV coaptation asymmetry measured from short-axis views on post-CPB TEE, is a strong predictor of recurrent AR requiring early

reoperation. Consideration should be given to return to bypass to improve coaptation symmetry in patients with a %diff-short of >50% on post-CPB TEE, even when the degree of residual AR is judged to be mild or less. Shorter coaptation height is also a marker of early valve failure. Future valve-root modeling procedures focusing on coaptation asymmetry and development of advanced analytical tools for evaluation of 3-dimensional dataset at the bedside may prove helpful for predicting need to revise the repair before leaving the operating room.

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Figure 1. Diagram showing echocardiographic measurements

Long-axis systole: A, B, length of anterior and posterior aortic leaflets; C, D, height of anterior and posterior sinuses of Valsalva; E, distance between aortic leaflet tips. Long-axis diastole: A, B, prolapse of anterior and posterior leaflets below annular plane; C, coaptation height; D, E, tip of leaflet coaptation to anterior and posterior aortic walls; Short-axis diastole: A, B and C, coaptation lengths; D, E and F, cusp areas.

Figure 2. Examples of %diff-short in a case and a control

The case has a %diff-short of 67% and clearly asymmetric coaptation. The %diff-short for the control is 15%, and the diastolic leaflet configuration appears more normal, with a central coaptation point.

Figure 3. Subject selection

Of 310 subjects identified by electronic database search, 266 were excluded: 186 had inadequate follow-up, 51 either had insufficient aortic regurgitation (AR) or severe aortic stenosis at baseline, 24 had a single ventricle, 3 underwent early reoperation – though not primarily for recurrent aortic regurgitation – and 2 underwent reoperation for predominant aortic regurgitation between 2–3 years.

Figure 4. Change in AR from intraoperative transesophageal echocardiogram to first postoperative transthoracic examination (TTE)

Among cases, the degree of AR increased by 1 grade in 12 (55%) and by 2 grades in 5 (23%). It was none or trivial in 2 patients (10%), mild in 14 (67%), moderate in 3 (14%) and severe in 3 (14%). In control patients, the degree of AR increased by 1 grade in 6 (27%) and decreased by 1 grade in 2 (9%). No controls patients experienced an increase in AR by 2 grades. Postoperative TTE AR grade was none or trivial in 9 patients (41%), and mild in 11 (50%). Postoperative TTEs were not performed in 2 control patients (9%).

Figure 5. Percent difference between longest and shortest short-axis coaptation lengths (%diff-short) in cases vs. controls

Boxplot demonstrating values for %diff-short in cases vs. controls. The area under the receiver operator curve for %diff-short was 0.743. Using a cutpoint of 50% for predicting recurrent AR requiring early reoperation, the sensitivity and specificity of this model were 0.45 and 0.91, respectively. An alternative cutpoint of 30% had a sensitivity of 0.75 and specificity of 0.67.

Table 1**Preoperative and Intraoperative Variables**

	Cases (n=22)	Controls (n=22)	<i>p</i> value
Male	16 (73%)	13 (59%)	0.53
Age (yrs)	11.0 (0.9–19.0)	13.0 (2.0–22.8)	0.34
Weight (kg)	39.4 (6.8–99.0)	35.2 (10.2–87.8)	0.99
Congenital AoV disease ^a	14 (64%)	18 (82%)	0.31
Prior AoV intervention	11 (50%)	13 (59%)	0.60
AoV morphology			0.33
Unicommissural	0 (0%)	2 (9%)	
Bicommissural	13 (59%)	11 (50%)	
Tricommissural	9 (41%)	7 (32%)	
Quadricommissural	0 (0%)	2 (9%)	
Connective tissue disease	4 (18%)	1 (5%)	0.34
Echocardiogram variables			
AS peak gradient (mm Hg)	24 (0–60), n=17	43 (10–63), n=17	0.03
LVEDV Z-score	6.1 (1.0–12.2), n=21	5.0 (2.7–9.5), n=18	0.85
LV ejection fraction (%)	60 (46–73), n=21	64 (51–74), n=18	0.12
Combined VC width/BSA (mm/m ²)	6.2 (2.0–9.7), n=21	4.7 (2.9–16.2), n=21	0.12
Aortic annulus diameter (cm)	2.4 (0.8–4.0)	2.1 (1.1–3.2)	0.20
Aortic root diameter (cm)	2.9 (1.3–4.6)	2.5 (1.6–3.7)	0.31
Magnetic resonance variables			
LVEDV index (mL/m ²)	155 (125–202), n=12	141 (105–170), n=11	0.12
AR fraction (%)	39 (26–59), n=12	40 (24–50), n=12	0.95
AR Grade			0.51
Moderate	14 (64%)	17 (77%)	
Severe	8 (36%)	5 (23%)	
AS Grade			0.20
None-to-trivial	13 (59%)	9 (41%)	
Mild	7 (32%)	6 (27%)	
Moderate	2 (9%)	7 (32%)	
Cardiopulmonary bypass time (min)	116 (44–306)	101 (62–190)	0.26
Aortic cross clamp time (min)	92 (28–186)	80 (47–156)	0.35
Additional procedures			0.05
Root/ascending aorta replacement	6 (27%)	1 (5%)	
Subaortic resection	0 (0%)	4 (18%)	
Leaflet augmentation/replacement	13 (59%)	19 (86%)	0.09
Additional bypass for AR	6 (27%)	6 (27%)	1.00

Data presented as median (range) or n (%)

AoV, aortic valve; AR, aortic regurgitation; AS, aortic stenosis; BSA, body surface area; LV, left ventricle; LVEDV, left ventricular end-diastolic volume; VC, vena contracta.

^a Cases: ventricular septal defect with aortic valve prolapse, atrioventricular canal, truncus arteriosus, tetralogy of Fallot, D-loop transposition of the great arteries, L-loop transposition of the great arteries, dilated aortic root, and hypertrophic cardiomyopathy. Controls: ventricular septal defect with aortic valve prolapse, transitional atrioventricular canal, truncus arteriosus and rheumatic heart disease.

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Table 2**Intraoperative Post-Cardiopulmonary Bypass Transesophageal Echocardiogram Variables**

	Cases (n=22)	Controls (n=22)	<i>p</i> value
Peak Doppler AS gradient (mm Hg)	14 (3 – 55), n=17	15 (5 – 30), n=19	0.79
Combined VC width/BSA (mm/m ²)	1.7 (0–6.0)	1.8 (0–5.4)	0.84
Combined VC area/BSA (cm ² /m ²)	0.09 (0–0.46)	0.10 (0–0.56)	0.88
AR grade			1.00
None-to-trivial	15 (68%)	14 (64%)	
Mild	7 (32%)	8 (36%)	
Aortic annulus diameter (cm)	2.0 (0.7–3.6)	1.9 (0.9–3.0)	1.00
% opening of aortic leaflet tips	81 (38–115)	80 (46–121), n=21	0.60
Aortic root diameter (cm)	2.4 (1.0–4.0)	2.3 (1.5–3.4)	0.82
Sinotubular junction (cm)	1.8 (0.9–2.9), n=18	1.7 (1.0–2.9), n=19	0.55
Anterior leaflet/anterior sinus (%)	71 (46–100), n=18	71 (50–116), n=21	0.92
Posterior leaflet/posterior sinus (%)	74 (45–101), n=18	77 (53–136), n=20	0.85
% diff-long	26 (7–143), n=21	21 (4–123)	0.07
Prolapse of anterior leaflet (mm)	3.1 (0–9.5)	2.0 (0–8.9)	0.03
Prolapse of posterior leaflet (mm)	4.1 (0–12.2)	3.3 (0–8.8)	0.19
Coaptation height (mm)	2.1 (–2.9–8.0), n=21	4.9 (0–9.1), n=21	0.01
Coaptation height/annulus diameter	0.16 (–0.27–0.38), n=21	0.27 (0–0.65), n=21	0.01
Height of base of coaptation (mm)	–0.7 (–6.5–0.8), n=21	–0.9 (–5.0–3.0)	0.32
Base of coaptation/annulus diameter	–0.06 (–0.60–0.03), n=21	–0.04 (–0.19–0.15)	0.16
Long-axis coaptation length (mm)	4.0 (2.0–7.2), n=21	5.6 (1.7–9.9), n=21	0.08
% diff-short	43 (14–94), n=20	26 (13–54), n=21	0.008
% difference cusp areas	51 (8–117), n=20	42 (3–116), n=21	0.66

Data presented at median (range) or number (%)

% diff-long, percent difference between distances from tip of coaptation to anterior and posterior aortic wall on long-axis views; %diff-short, percent difference between longest and shortest coaptation lengths on short-axis views; AR, aortic regurgitation; AS, aortic stenosis; BSA, body surface area; VC, vena contracta.

Table 3**Univariate Risk Factors for Early Reoperation for Recurrent Aortic Regurgitation**

		OR	95% CI	p value
Preoperative variables				
Connective tissue disease		4.67	0.48–45.62	0.19
MRI LVEDV index (ml/m ²)	↑10	1.34	0.95–1.91	0.10
Echo AS peak gradient (mm Hg)	↑1	0.95	0.91–0.99	0.02
Echo LV EF (%)	↓5	1.50	0.93–2.41	0.10
Combined VC width/BSA (mm/m ²)	↑1	1.05	0.83–1.32	0.71
Consensus AS grade Mild vs. None/Trivial		0.81	0.20–3.22	0.76
Consensus AS grade Moderate vs. None/Trivial		0.20	0.03–1.18	0.08
Operative variables				
Valve-sparing aortic replacement ^a		17.73	1.04–>999	0.04
Subaortic Resection ^a		0.09	<0.01–0.94	0.04
Cardiopulmonary bypass time (min)	↑10	1.10	0.96–1.27	0.18
Cross clamp time (min)	↑10	1.11	0.92–1.34	0.27
Leaflet augmentation/replacement		0.23	0.05–1.01	0.05
Intraoperative TEE variables				
%diff-long	↑10	1.15	0.95–1.40	0.15
Prolapse of anterior leaflet (mm)	↑1	1.32	0.99–1.77	0.06
Prolapse of posterior leaflet (mm)	↑1	1.18	0.93–1.51	0.18
Coaptation height (mm)	↑1	0.72	0.54–0.95	0.02
Coaptation height/annulus diameter (%)	↓5	1.37	1.06–1.77	0.02
Base of coaptation/annulus diameter (%)	↓5	1.37	0.98–1.91	0.06
Long-axis coaptation length (mm)	↑1	0.74	0.52–1.04	0.09
%diff-short	↑10	1.84	1.15–2.92	0.01

%diff-long, percent difference between distances from tip of coaptation to anterior and posterior aortic wall on long-axis views; %diff-short, percent difference between longest and shortest coaptation lengths on short-axis views; AS, aortic stenosis; BSA, body surface area; CI, confidence interval; LVEDV, left-ventricular end-diastolic volume; OR, odds ratio; MRI, magnetic resonance imaging; TEE, transesophageal echocardiography; VC, vena contracta.

^aFirth logistic regression was used to correct for potential bias in the OR and CI.