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Original Research

Evaluating Procedural Performance: A Composite Outcome for Aortic and Pulmonary Valvuloplasty in Congenital Cardiac Catheterization

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ABSTRACT

Background: Safety events and technical success (TS) have been previously reported for aortic and pulmonary valvuloplasty, but a composite performance measure as a novel, patient-centered strategy has neither been developed nor been studied. This study aims to refine a procedural performance (PP) variable, a composite of TS and procedural safety, for isolated, standard-risk aortic and pulmonary valvuloplasty.

Methods: A multicenter review was performed using data from the Congenital Cardiac Catheterization Project on Outcomes registry. Data were collected for all cases of isolated balloon aortic and pulmonary valvuloplasty from 2014 through 2017. Patients were excluded if they were aged <1 month, were inpatient at the time of the procedure, or had significant comorbidities, such as Williams or Noonan syndrome. Criteria for TS were developed and categorized (optimal, satisfactory, and unsatisfactory) by expert consensus based on previous outcome research. Adverse events (AE) were categorized by severity (level 1-5) using established criteria. Level 4 and 5 severity AE were considered high-severity AE. Using criteria of TS and AE severity, PP was divided into 3 composite outcome classes. Factors correlating with class III (suboptimal) PP were analyzed.

Results: There were 169 cases of aortic and 270 cases of pulmonary valvuloplasty in the cohorts. In the aortic valvuloplasty cohort, a suboptimal PP (class III) occurred in 14% of cases, mostly due to high-severity AE (7%). No significant correlation between patient or case characteristics and PP was demonstrated. In the pulmonary valvuloplasty cohort, class III PP occurred in 9% of cases, predominantly due to residual valve gradient, which correlated with lower weight ($P = .02$).

Conclusions: We designed a composite variable of PP consisting of TS and safety as a comprehensive measure of outcome. Incorporating both TS and AE may better reflect patient outcome than each metric measured separately. PP indices may identify areas for further investigation and quality improvement.

Abbreviations: AE, adverse event; BAVP, balloon aortic valvuloplasty; BPVP, balloon pulmonary valvuloplasty; C3PO, Congenital Cardiac Catheterization Project on Outcomes; HSAE, high-severity adverse event; LOS, length of stay; PP, procedural performance; TS, technical success; WG, working group.

Keywords: aortic balloon valvuloplasty; procedural performance; pulmonary balloon valvuloplasty.

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Introduction

Previous outcome research for congenital cardiac catheterization procedures has provided critical data on both the safety of procedures and the technical success (TS) of various interventions.[1-9] These data have informed changes in clinical practice to improve safety and TS. These outcome variables have only been evaluated independently, highlighting the need for a composite variable to evaluate comprehensive procedural performance (PP). This would add significant value along with an opportunity to optimize interventional procedures, as has been done in the field of congenital heart surgery.[10-12]

Although such a composite variable—using a combination of hemodynamic and echocardiographic data, elective patient discharge, and adverse event (AE) severity—of procedural efficacy for pulmonary and aortic valvuloplasty is currently used in the International Quality Improvement Collaborative Congenital Heart Disease Catheterization Registry,[13] this metric has not been validated in a large data set. Furthermore, improvements within the various components of the variable may be necessary, as well as detailed description of its categories.

The aim of this project was to revise the International Quality Improvement Collaborative Congenital Heart Disease Catheterization Registry composite PP variable and its categories in patients who underwent isolated balloon aortic valvuloplasty (BAVP) or balloon pulmonary valvuloplasty (BPVP) procedures, focusing on patients with limited complexity, and then validate it retrospectively using the Congenital Cardiac Catheterization Project on Outcomes (C3PO) (https://c3po-r3.chboston.org) data set.[14] We also sought to determine patient and procedural characteristics and risk factors that correlated with suboptimal PP.

Methods

Variable development

In order to create a composite variable, criteria for both TS and safety events needed to be developed. An expert panel of physicians from participating sites was assembled as a working group (WG) to develop this novel outcome variable. The previously published composite PP variable formed a foundation for this process.[13] Previously published technical metrics and short- and long-term patient outcomes were assessed and are summarized in Supplemental Table S1.[1,3,4,7,15-17] Data are notably lacking on such technical metrics or PP variables; thus, expert opinion from the WG, including opinion polls, was the main source of creating and modifying this composite variable. Criteria acceptable to >80% of the WG were included.

For TS, criteria were developed using 2 components: (1) residual peak-to-peak gradients measured during the cardiac catheterization and (2) change in valvar regurgitation after valvuloplasty assessed either angiographically or on echocardiogram. TS was categorized as optimal, satisfactory, or unsatisfactory (Table 1). For safety elements, AE were self-reported by participating sites, with severity level and categorization as previously described.[18-20] AE with severity levels 3 to 5 were considered severe, and events of severity levels 4 and 5 were additionally labeled as high-severity AE (HSAE). AE categorization and severity scoring were independently reviewed for accuracy and consistency as part of the standard audit process performed by C3PO. These AE were not risk-adjusted.

By combining TS and safety criteria, PP was categorized into 3 classes (I to III) (Table 1), with class I achieving an ideal outcome and class III being suboptimal. All criteria must have been met for the PP to be designated class I, while any single criterion within class III deemed the case to be suboptimal (ie, class III).

Case selection and data collection

A multicenter review was performed using data from the C3PO registry. Data were collected for all cases of isolated, standard-risk BAVP and BPVP from 2014 through 2017. Patients were excluded if they were aged <1 month, were inpatient at the time of the procedure, had significant comorbidities or an associated genetic syndrome, such as Williams or Noonan syndrome.

Patient data included sex and age/weight at catheterization. Procedure-specific data included valve morphology, preintervention and postintervention valvar gradients and degree of regurgitation, and AE details. Outcome variables included length of stay (LOS) and unplanned or emergent surgery or death within 72 hours of the cardiac catheterization procedure.

Table 1. Criteria for technical success and procedural performance.

Procedure			
Balloon aortic valvuloplasty			
Technical success	Optimal[a] • Residual PSEG <35 mm Hg • No worsening AR	Satisfactory[b] • PSEG 35-50 mm Hg • Worsening of AR by 1 level compared to baseline	Unsatisfactory[b] • PSEG ≥50 mm Hg • Worsening AR by ≥2 levels compared to baseline or severe AR
Procedural performance	Class I[a] • Optimal TS • AES 1 and 2 • Elective home discharge	Class II[b] • Optimal or satisfactory TS • AES 3	Class III[b] • Unsatisfactory TS with any AES • Any TS with AES 4 and 5
Balloon pulmonary valvuloplasty			
Technical success	Optimal[a] • Residual valvar PSEG <20 mm Hg • No worsening PR	Satisfactory[b] • Residual valvar PSEG 20-40 mm Hg • Worsening of PR by 1 level compared to baseline	Unsatisfactory[b] • Residual valvar PSEG ≥40 mm Hg • Worsening PR by ≥2 levels compared to baseline or severe PR
Procedural performance	Class I[a] • Optimal TS • AES 1 and 2 • Elective home discharge	Class II[b] • Optimal or satisfactory TS • AES 3	Class III[b] • Unsatisfactory TS with any AES • Any TS with AES 4 and 5

AES, adverse event severity; AR, aortic regurgitation; PR, pulmonary regurgitation; PSEG, peak systolic gradient.
[a] All criteria need to be met. [b] A single criterion in this category determines classification.

Statistical analysis

Patient characteristics and outcomes were summarized for subjects in the aortic and pulmonary valvuloplasty cohorts separately. Frequencies and percentages were used for categorical variables, and medians with interquartile ranges (IQR) of 25th and 75th percentiles were used for continuous variables. In order to investigate factors associated with suboptimal efficacy within each cohort, patients with class III PP were compared to those with classes I and II combined using the Fisher exact test or the Wilcoxon rank-sum test. Analyses were performed using Stata version 16 (StataCorp).

This study was approved by the Boston Children's Hospital Institutional Review Board and was supported by data-sharing agreements between the Boston Children's Hospital and the C3PO participating sites as required.

Results

A total of 284 cases of BAVP and 641 cases of BPVP were entered in the C3PO registry during the study period. Of these, 40% of the BAVP cases and 57% of the BPVP cases were excluded, primarily due to patients being <30 days of age at the time of the procedure (Figure 1A, B). Thus, a total of 169 BAVP and 270 BPVP cases were studied. TS and PP were evaluated in 157 BAPV and 200 BPVP procedures due to availability of data related to the metric.

BAVP

The median age at catheterization was 9.4 years (IQR, 0.7-14.3), with a median weight of 34 kg (IQR, 8.8-59) (Table 2). Of the BAVP cases, 91% (n = 143) had optimal or satisfactory TS (Table 3). Among those who had unsatisfactory TS, 6 (4%) cases had a residual gradient of ≥50 mm Hg and 8 (5%) had a significant (ie, more than 2 levels from baseline or severe) increase in the degree of aortic regurgitation (Supplemental Table S2). During the audit process, 2 patients who developed severe regurgitation were deemed to be in need of early but nonemergent intervention to manage the regurgitation. These patients were thus considered to have a level 4 severity AE. There were no level 5 AE (ie, mortality or unplanned/emergent surgery). The median LOS following BAVP was 1 day.

Class I and II PP was achieved in the majority of patients (n = 136, 87%) undergoing BAVP (Central Illustration). Among the 21 (13%) patients who had class III PP, 50% of the cases of class III PP were due to a level 4 AE (Table 3 and Figure 2). The most common HSAE was cardiac arrest requiring defibrillation and/or chest compressions (60% of HSAE). Other HSAE were related to complications with the access site, such as pseudoaneurysm (n = 1) and arterial occlusion (n = 1) requiring surgical intervention (Table 4).[21] There were no differences in the preprocedural patient characteristics, valve function, or anatomy between cases with class III PP and class I/II PP (Table 5).

BPVP

Patients had a median age of 0.6 years (IQR, 0.3-3.5), and a median weight of 7.7 kg (IQR, 5.7-17), at the time of BPVP (Table 2). Of these patients, 91% (n = 182) achieved optimal and satisfactory TS (Table 3). Unsatisfactory TS occurred in 18 patients (9%) due to a residual gradient of ≥40 mm Hg (n = 14, 7%) or an increase in pulmonary valve regurgitation by at least 2 levels (n = 4, 2%) (Supplemental Table S3). The

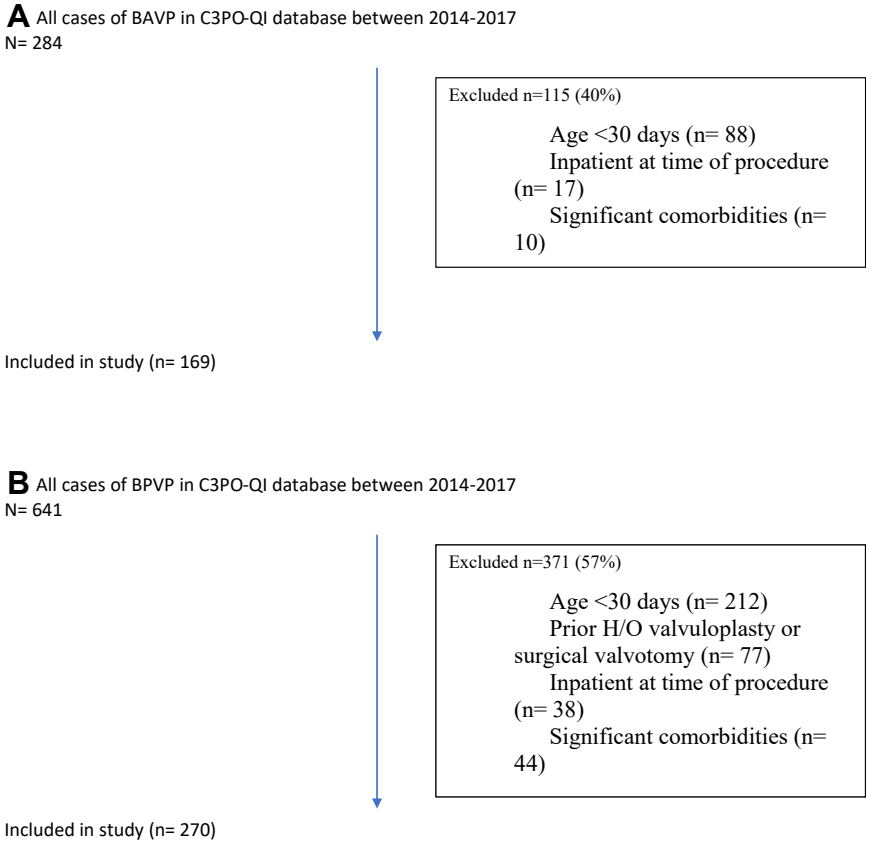


Figure 1.
Flowchart for included and excluded patients. (**A**) All cases of balloon aortic valvuloplasty (BAVP) in Congenital Cardiac Catheterization Project on Outcomes- Quality Improvement (C3PO-QI) database from 2014 through 2017 (N = 284). (**B**) All cases of BPVP (balloon pulmonary valvuloplasty) in C3PO-QI database from 2014 through 2017 (N = 641). H/O, history of.

Table 2. Patient characteristics by the valvuloplasty cohort.

	BAVP (n = 169)	BPVP (n = 270)
Male sex	125 (74)	121 (45)
Age at catheterization, y	9.4 (0.7-14.3)	0.6 (0.3-3.5)
Weight at catheterization, kg	34 (8.8-59)	7.7 (5.7-17)

Values shown are number (percent) or median (25th to 75th percentiles).
BAVP, balloon aortic valvuloplasty; BPVP, balloon pulmonary valvuloplasty.

Table 3. Outcomes by valvuloplasty cohort.

	Balloon aortic valvuloplasty (n = 169)	Balloon pulmonary valvuloplasty (n = 270)
Technical success		
Optimal	91/157 (58)	90/200 (45)
Satisfactory	52/157 (33)	92/200 (46)
Unsatisfactory	14/157 (9)	18/200 (9)
Length of stay, d	1 (1-1)	1 (0-1)
Unplanned catheterization or surgery	0 (0)	0 (0)
Any level 4/5 adverse event	11 (6.5)	0 (0)
Death within 72 h	0 (0)	0 (0)
Procedural performance		
Class I	52/157 (33)	86/200 (43)
Class II	84/157 (54)	96/200 (48)
Class III	21/157 (13)	18/200 (9)

Values shown are number (percent) or median (25th to 75th percentiles).

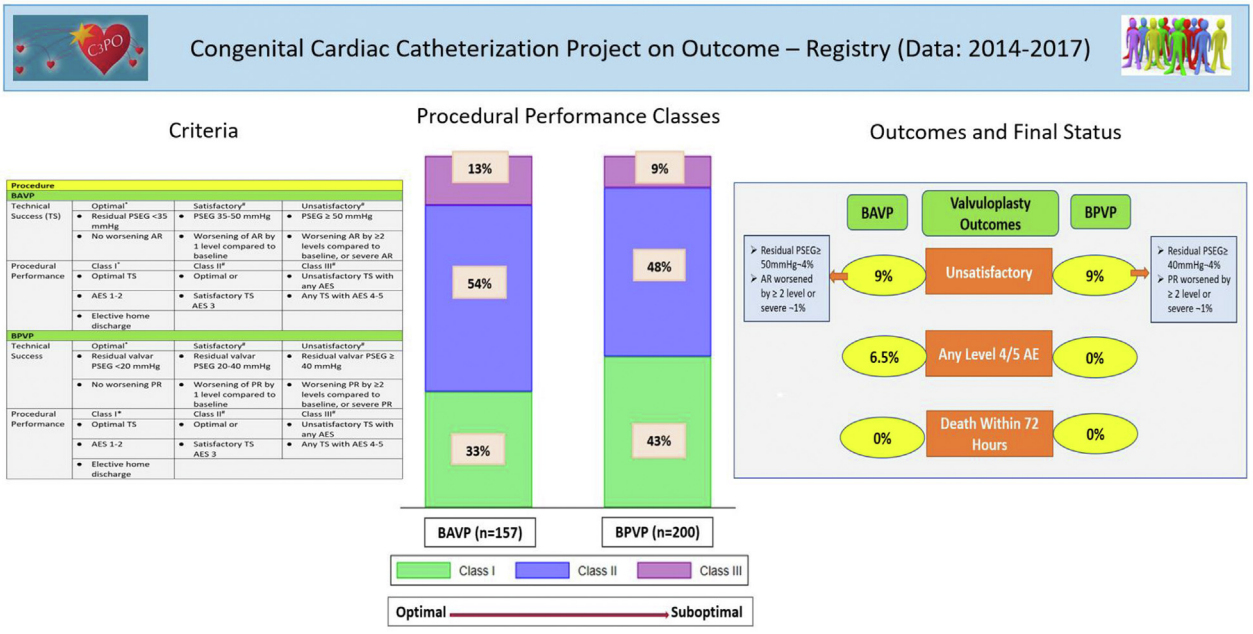
median LOS after BPVP was 1 day, and there were no unplanned operations or catheterizations after the procedure.

Similar to TS, class I and II PP was achieved in the majority (n = 182, 86%) of patients. As opposed to BAVP, class III PP was exclusively affected by the technical outcome because there were no HSAE reported among these 18 (9%) patients (Tables 3 and 4, Central Illustration, and Figure 2). Lower weight and patients with no baseline pulmonary regurgitation (PR) were more likely to have class III PP (Table 6).

Discussion

A composite outcome variable, PP, was developed using limited available data, broad user experience, and knowledge with widespread agreement among our WG. When evaluated using this variable, patients undergoing balloon valvuloplasty for standard-risk aortic and pulmonary valve stenosis demonstrated excellent outcomes. An unsatisfactory TS (due to postvalvuloplasty valve dysfunction) or HSAE led to class III (suboptimal) PP in patients who underwent BAVP. None of the available patient or procedural characteristics correlated with class III PP. In patients undergoing BPVP, postprocedural valve dysfunction contributed to all the cases with unsatisfactory TS and class III PP. In these patients, lower weight at the time of procedure correlated with suboptimal performance due to residual gradient.

A useful process and outcome metric should reflect increasing case complexity and modifiable risk factors, be predictive of short- and long-term patient health status, and show change through quality improvement efforts. In this study, the composite outcome of PP was evaluated in standard-risk cases of isolated aortic and pulmonary valvuloplasty in patients with no comorbidities in order to limit confounding variables and illustrate the face validity of this variable. The TS and safety of these procedures in this study cohort were indeed similar to those in other published cohorts and thus showed predominantly class I and II outcomes for both procedures. The hospital LOS was also short and there were no unexpected surgeries, reflective of the low-risk patient cohort included in this study. Although the validity of this variable needs to be tested for complex procedures, it is encouraging to see its performance in the cohort selected for this study. Future development of PP for complex procedures and studies including patients who may be at higher risk (eg, neonates and patients with ventricular dysfunction or complex outflow tract obstruction) may help in the applicability of this composite variable for complex procedures and high-risk patient populations. Additionally, correlating this variable with hospital LOS,



Central Illustration.
Procedural (valvuloplasty) performance criteria, classes, and outcomes. *All criteria need to be met. #A single criterion in the highest class determines classification. AE, adverse event; AES, adverse event severity; AR, aortic regurgitation; BAVP, balloon aortic valvuloplasty; BPVP, balloon pulmonary valvuloplasty; PR, pulmonary regurgitation; PSEG, peak systolic gradient; TS, technical success.

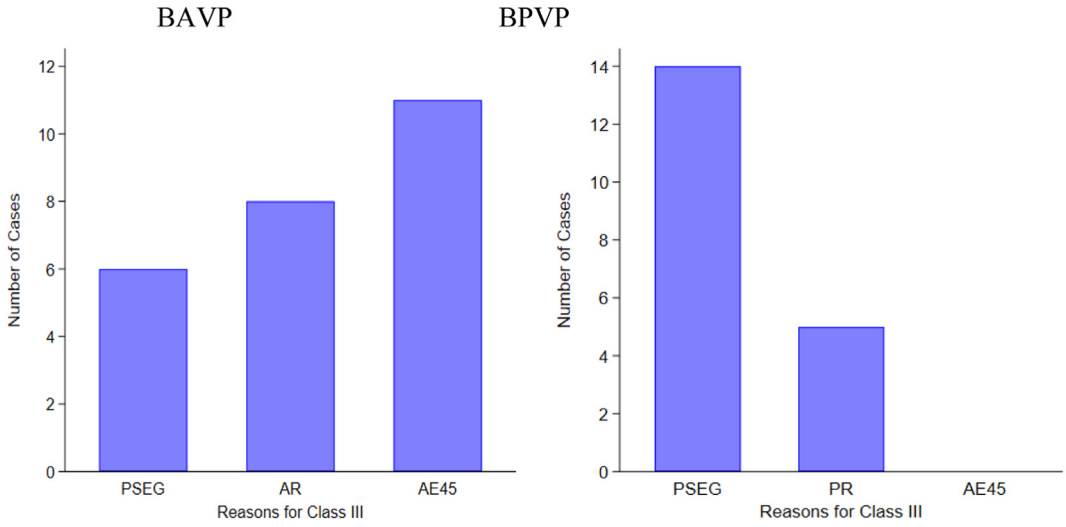


Figure 2.
Reason for class III procedural performance in balloon aortic valvuloplasty (BAVP) and balloon pulmonary valvuloplasty (BPVP). X-axis indicates the reason for class III procedural performance, and Y-axis indicates the number of patients. AE, adverse event; AR, aortic regurgitation; PR, pulmonary regurgitation; PSEG, peak systolic gradient.

unplanned surgery, or death within 72 hours of catheterization may also help in using this variable as a predictor of immediate patient outcome after valvuloplasty. Databases that include long-term follow-up of patients will be needed to study the effect of such performance variables on freedom from reintervention, postdischarge morbidity or mortality, and patient-reported outcomes.

The causes of a class III PP are potentially quite variable. Therefore, rather than simply identifying the outcome as suboptimal, the PP variable allows us to understand the major category to address to improve future outcomes and for optimizing informed consent. Reasons for class III PP in BAVP were HSAE (mainly ventricular arrhythmia requiring cardioversion) or worsening regurgitation. The risk of hemodynamically significant arrhythmia during BAVP cases is a well-described complication and highlights the need for proper anticipation and preparation (ie, role assignment during cardiopulmonary resuscitation and availability and appropriate use of a defibrillator during BAVP procedure). Quality improvement strategies can be adopted to help decrease such events or improve the success of rescuing a patient during such a life-threatening event. Longer freedom from aortic valve replacement has been associated with lower postvalvuloplasty gradient (peak gradient, <35 mm Hg) and/or regurgitation (less than moderate).[10] Factors such as larger valvuloplasty balloon (determined by balloon-to-annulus ratio)[22] and aortic valve leaflet morphology may determine the risk of regurgitation after valvuloplasty.[23] In our study, we were unable to identify any factors associated with class III PP in BAVP, including valve morphology. A larger cohort of patients may be needed to study such risk factors and help identify areas of improvement. Suboptimal (class III) PP in patients undergoing BPVP was due to residual gradient across the right ventricular outflow tract. This PP was significantly associated with lower weight of the patients. These may be attributable to a more severe disease process consisting of dysplastic valves, complex right ventricular outflow tract obstruction, and/or genetic syndromes that are less likely to respond to BPVP. More details regarding the level of the obstruction (valvar vs subvalvar) and procedural characteristics, such as balloon-to-annulus ratio, may be needed to create strategies to improve this outcome. Additionally, class III PP also correlated with absence of PR before intervention. Class III PP in BPVP was attributed to residual gradient in 14 of the 18 patients, whereas in the remaining cases, it was an increase in PR by ≥2 levels. With limited data, clinical inference of this correlation is difficult to ascertain.

Table 4. Adverse events during valvuloplasty.

Type of adverse event[a]	BAVP	BPVP
Severity level 3	n = 9	n = 6
Ventricular arrhythmia not requiring cardioversion/defibrillation	2	0
New valvar regurgitation not resulting in hemodynamic instability or requiring surgical intervention	3	
Vascular access–related complications, including vessel thrombosis, vessel injury, and hemodynamically tolerated retroperitoneal hemorrhage	3	1
Atrial arrhythmias requiring medical and/or electrical cardioversion	1	5
Severity levels 4 and 5	n = 11	n = 0
Ventricular arrhythmia needing resuscitation or cardioversion/defibrillation	5	
Angioplasty-related complications resulting in significant vascular injury or hemodynamic instability	2	
Cardiac arrest requiring cardiopulmonary resuscitation or extracorporeal membrane oxygenation	1	
Vascular access–related complications or vessel injuries that are deemed life-threatening and/or requiring surgical intervention	3	

BAVP, balloon aortic valvuloplasty; BPVP, balloon pulmonary valvuloplasty.
[a] Adapted from Quinn et al.[21]

Table 5. Factors associated with class III procedural performance (balloon aortic valvuloplasty).

	Class I/II (n = 136)	Class III (n = 21)	*P* value
Male sex	104 (76)	14 (67)	.42
Age at catheterization, y	10.9 (0.6-14.4)	7.4 (0.6-13.5)	.56
Weight at catheterization, kg	40.6 (8.4-59.0)	24.3 (8.8-56.0)	.52
Preintervention systolic gradient, mm Hg	55 (48-63)	55 (50-68)	.76
Preintervention aortic regurgitation			.59
None	82 (60)	13 (62)	
Mild	47 (35)	6 (29)	
Moderate	7 (5)	2 (9)	
Valve morphology			.25
Unicuspid	28 (21)	2 (9)	
Bicuspid	104 (78)	18 (86)	
Tricuspid	2 (1)	1 (5)	

Values shown are number (percent) or median (25th to 75th percentiles). Comparisons were made using the Fisher exact test or the Wilcoxon rank-sum test.

Table 6. Factors associated with class III procedural performance (balloon pulmonary valvuloplasty).

	Class I/II (n = 182)	Class III (n = 18)	*P* value
Male sex	88 (49)	9 (50)	1.0
Age at catheterization, y	0.6 (0.3-4.3)	0.3 (0.2-0.8)	.062
Weight at catheterization, kg	8.3 (5.8-17.6)	6.1 (5.3-7.1)	.015
Preintervention pulmonary regurgitation			.036
None	141 (77)	16 (94)	
Mild	38 (21)	0 (0)	
Moderate-severe	3 (2)	1 (6)	
Valve morphology dysplastic/complex	74 (41)	11 (61)	.14

Values shown are number (percent) or median (25th to 75th percentiles). Comparisons were made using the Fisher exact test or the Wilcoxon rank-sum test.

There are several limitations to our work. First, the evidence base supporting our composite variable was insufficient, so we relied on the consensus achieved within our WG. The composite variable was then evaluated on a retrospective data set. There are limitations that are associated with a retrospective study design. Additional research is necessary to evaluate the validity of the composite variable, potentially in a prospective study with longitudinal data collection. Second, restricting the patient cohort in this study to those without "high-risk" features who underwent isolated valvuloplasty procedures limits generalizability, and the results cannot be extrapolated to patients with complex outflow tract obstruction. Lack of a core laboratory and standardized definitions may cause interobserver variability in the interpretation of the data, such as degree of valvar regurgitation, assessment of gradients, and description of valve morphology. Finally, this outcome was introduced using a limited retrospective data set. Evaluation of specific variables, such as genetic disorders, and procedural details and its relationship with PP may provide more insight into both standard and high-risk patients.

Future work could entail validating this variable on more complex cohorts for better generalizability, determining the ability of this variable in discriminating between high- and low-risk cases, and studying the effect of the variable in predicting short- and long-term patient outcomes and freedom from reinterventions. Similar composite variables using our methodology can be developed for other interventional procedures, such as patent ductus arteriosus stenting, branch pulmonary artery interventions, coarctation stenting/dilation, etc.

Conclusion

A composite variable of PP, consisting of TS and safety, was successfully designed as a comprehensive measure of outcome. As expected, a majority of the isolated BAVP and BPVP procedures had excellent PP. Our new metric of PP, rather than simply identifying the outcome as suboptimal, allows us to understand the major category (TS vs AE) that can be addressed to improve outcomes and better guide informed consent.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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None.

Ethics statement and patient consent

The authors declare that all procedures contributing to this work comply with the ethical standards of the relevant national guidelines on human experimentation and with the Helsinki Declaration of 1975 and that the study was approved by the Boston Children's Hospital Institutional Review Board and was supported by data-sharing agreements between Boston Children's Hospital and the relevant institutional committees at all the C3PO participating sites.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101119.

References

1. Holzer RJ, Gauvreau K, Kreutzer J, et al. Safety and efficacy of balloon pulmonary valvuloplasty: a multicenter experience. *Catheter Cardiovasc Interv*. 2012;80(4):663–672. https://doi.org/10.1002/ccd.23473
2. Charafeddine FA, Houssein HB, Kibbi NB, et al. Balloon valvuloplasty for congenital aortic stenosis: experience at a tertiary center in a developing country. *J Interv Cardiol*. 2021;2021:6681693. https://doi.org/10.1155/2021/6681693
3. Boe BA, Zampi JD, Kennedy KF, et al. Acute success of balloon aortic valvuloplasty in the current era: a National cardiovascular Data Registry study. *J Am Coll Cardiol Intv*. 2017;10(17):1717–1726. https://doi.org/10.1016/j.jcin.2017.08.001
4. Torres A, Vincent JA, Everett A, et al. Balloon valvuloplasty for congenital aortic stenosis: multi-center safety and efficacy outcome assessment. *Catheter Cardiovasc Interv*. 2015;86(5):808–820. https://doi.org/10.1002/ccd.25969
5. Kenny DP, Hijazi ZM. Current status and future potential of transcatheter interventions in congenital heart disease. *Circ Res*. 2017;120(6):1015–1026. https://doi.org/10.1161/CIRCRESAHA.116.309185
6. Jayaram N, Spertus JA, Kennedy KF, et al. Modeling major adverse outcomes of pediatric and adult patients with congenital heart disease undergoing cardiac catheterization: observations from the NCDR Impact Registry (National cardiovascular Data Registry Improving Pediatric and Adult Congenital Treatment). *Circulation*. 2017;136(21):2009–2019. https://doi.org/10.1161/CIRCULATIONAHA.117.027714
7. Porras D, Brown DW, Rathod R, et al. Acute outcomes after introduction of a standardized clinical assessment and management plan (SCAMP) for balloon aortic valvuloplasty in congenital aortic stenosis. *Congenit Heart Dis*. 2014;9(4):316–325. https://doi.org/10.1111/chd.12142
8. O'Byrne ML, Huang J, Asztalos I, et al. Pediatric/congenital cardiac catheterization quality: an analysis of existing metrics. *J Am Coll Cardiol Intv*. 2020;13(24):2853–2864. https://doi.org/10.1016/j.jcin.2020.09.002
9. Hunter S, Wren C. Balloon dilatation in congenital heart disease. *Arch Dis Child*. 1987;62(8):768–770. https://doi.org/10.1136/adc.62.8.768
10. Karamichalis JM, Colan SD, Nathan M, et al. Technical performance scores in congenital cardiac operations: a quality assessment initiative. *Ann Thorac Surg*. 2012;94(4):1317–1323. https://doi.org/10.1016/j.athoracsur.2012.05.014. discussion 1323.
11. Larrazabal LA, del Nido PJ, Jenkins KJ, et al. Measurement of technical performance in congenital heart surgery: a pilot study. *Ann Thorac Surg*. 2007;83(1):179–184. https://doi.org/10.1016/j.athoracsur.2006.07.031
12. Nathan M, Karamichalis JM, Liu H, et al. Surgical technical performance scores are predictors of late mortality and unplanned reinterventions in infants after cardiac surgery. *J Thorac Cardiovasc Surg*. 2012;144(5):1095–1101.e7. https://doi.org/10.1016/j.jtcvs.2012.07.081
13. Barry OM, Ali F, Ronderos M, et al. Pilot phase experience of the International quality improvement collaborative catheterization registry. *Catheter Cardiovasc Interv*. 2021;97(1):127–134. https://doi.org/10.1002/ccd.28908
14. Chaudhry-Waterman N, Coombs S, Porras D, Holzer R, Bergersen L. Developing tools to measure quality in congenital catheterization and interventions: the congenital cardiac catheterization project on outcomes (C3PO). *Methodist deBakey Cardiovasc J*. 2014;10(2):63–67. https://doi.org/10.14797/mdcj-10-2-63
15. McCrindle BW. Independent predictors of long-term results after balloon pulmonary valvuloplasty. Valvuloplasty and angioplasty of congenital anomalies (VACA) registry investigators. *Circulation*. 1994;89(4):1751–1759. https://doi.org/10.1161/01.cir.89.4.1751
16. Latson LA. Balloon pulmonary valvuloplasty, pulmonary regurgitation, and exercise capacity: the good, the bad, and the not yet clear. *J Am Coll Cardiol*. 2010;55(10):1048–1049. https://doi.org/10.1016/j.jacc.2010.01.017. American College of Cardiology Foundation.

17. Holzer RJ, Cheatham JP. Shifting the balance between aortic insufficiency and residual gradients after balloon aortic valvuloplasty. *J Am Coll Cardiol*. 2010; 56(21):1750–1751. https://doi.org/10.1016/j.jacc.2010.07.024
18. Bergersen L, Gauvreau K, Jenkins KJ, Lock JE. Adverse event rates in congenital cardiac catheterization: a new understanding of risks. *Congenit Heart Dis*. 2008; 3(2):90–105. https://doi.org/10.1111/j.1747-0803.2008.00176.x
19. Bergersen L, Marshall A, Gauvreau K, et al. Adverse event rates in congenital cardiac catheterization—a multi-center experience. *Catheter Cardiovasc Interv*. 2010;75(3):389–400. https://doi.org/10.1002/ccd.22266
20. Bergersen L, Gauvreau K, Foerster SR, et al. Catheterization for congenital heart disease adjustment for risk method (CHARM). *J Am Coll Cardiol Intv*. 2011;4(9): 1037–1046. https://doi.org/10.1016/j.jcin.2011.05.021
21. Quinn BP, Yeh M, Gauvreau K, et al. Procedural risk in congenital cardiac catheterization (PREDIC^{3}T). *J Am Heart Assoc*. 2022;11(1):e022832. https://doi.org/10.1161/JAHA.121.022832
22. Auld B, Carrigan L, Ward C, Justo R, Alphonso N, Anderson B. Balloon aortic valvuloplasty for congenital aortic stenosis: a 14-year single centre review. *Heart Lung Circ*. 2019;28(4):632–636. https://doi.org/10.1016/j.hlc.2018.02.014
23. Petit CJ, Gao K, Goldstein BH, et al. Relation of aortic valve morphologic characteristics to aortic valve insufficiency and residual stenosis in children with congenital aortic stenosis undergoing balloon valvuloplasty. *Am J Cardiol*. 2016;117(6):972–979. https://doi.org/10.1016/j.amjcard.2015.12.034