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The CHD severity classification system: development of a tool to assist with disease stratification for CHD research

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Abstract

Background: Complexity stratification for CHD is an integral part of clinical research due to its heterogenous clinical presentation and outcomes. To support our ongoing research efforts into CHD requiring disease severity stratifications, a simplified CHD severity classification system was developed and verified, with potential utility for clinical researchers without specialist CHD knowledge or access to clinical/medical records. *Method:* A two-tiered analysis approach was undertaken. First-tier analysis included the audit of a comprehensive system based on: i) timing of intervention, ii) cardiac morphology, and iii) cardiovascular physiology using real patient data (n = 30), across 10 common CHD lesions. Second-tier analysis allowed for a simplified version of the classification system using morphology as a stand-alone predictor. Twelve clinicians of varying specialities involved in CHD care ranked 10 common lesions from least to most severe based on typical presentation and clinical course. *Results:* First-tier analysis identified that cardiac morphology was the principal driver of complexity. Second-tier analysis largely confirmed the ranking and classification of the lesions into the broad CHD severity groups, although some variation was noted, specifically among non-cardiac specialists. This simplified version of the classicisation system, with morphology as a stand-alone predictor of severity, allowed for effective stratification for the purposes of analysis. *Conclusion:* The findings presented here support this comprehensive and simple CHD severity classification system with broad utility in CHD research, particularly among clinicians and researchers with limited knowledge of CHD. The model may be applied to produce locally relevant research tools.

Introduction

CHD encompasses a broad range of structural abnormalities of the heart and/or great vessels present at birth.[1] It is the most prevalent type of congenital anomaly, affecting an estimated 9.4 /1000 live births worldwide and is associated with significant mortality and morbidity.[1,2] CHD is heterogenous in clinical presentation, management, and clinical outcome. Approximately a third of all children with CHD will require surgical or catheter interventions,3 with approximately one-quarter of those needing surgery within the first year of life, necessitating lifelong monitoring of the cardiac condition and associated comorbidities. Some types of CHD may not require any intervention.[3] CHD is multifaceted with great variance in morbidity across the many lesion types.

As a result of the heterogeneity observed in CHD, complexity stratification systems have been developed that incorporate various clinical and morphological factors in an effort to stratify patients into complexity groups.[4–15] These factors include cardiac anatomy, life expectancy, quality of life, level of predicted morbidity, interventions, psychological wellbeing, and projected life limitations. Such systems are largely intended for clinical use at the bedside and primarily focus on adult CHD.[4,11,12,9] A commonly used classification system is Task Force 1 of the 32nd Bethesda Conference, which classifies CHD into three categories including great complexity, moderate severity, and simple CHD.[11] However, to date, no classification system has been adopted widely, likely reflecting variations in practice and an appreciation for the many contributory factors of CHD severity.

Established CHD severity classification systems are often complex and time-intensive and typically require specialist CHD and/or clinical knowledge. Further, they require access to patient medical records, to retrieve the necessary detailed clinical data required to classify patients. This is a limitation because patient medical records are not always accessible to researchers due to ethical constraints and limits to collaboration across multiple groups/institutions. Further, non-cardiac clinical staff and researchers often lack the specialist cardiac-specific knowledge required to assist with the classification process. This poses a barrier to researchers who require CHD severity classifications. A CHD classification system may be

useful for genomics research, clinical outcomes studies, and psychosocial and epidemiology studies.

To support our ongoing research efforts into CHD requiring disease severity stratifications, a purpose-designed CHD severity classification system was developed for researchers without specialist CHD knowledge or access to patient medical records. The reason for the development of this system, in the context of other classification systems being available, was to test to what degree a titrated, simplified classification could address the needs of our researchers working with our study population. Subsequent to the development of this system, the classification was used to categorise a large cohort of CHD patients into groups according to disease severity for genomic, epidemiological, and clinical outcomes-based studies.[16] This system is intended to simplify severity classification in CHD and is based on the primary CHD lesion, for broad clinical categories. It includes a comprehensive and simplified version, depending on the research question, the level of clinical knowledge of the researchers, the level of distinction of the lesion required, and the availability and/or accessibility of patient medical records.

Materials and method

A two-tiered analysis approach was applied to the development and assessment of the CHD severity classification system.

Development and analysis of the comprehensive CHD severity classification system

First-tier analysis involved the development of a comprehensive classification system focussing on three main criteria: i) timing of intervention, ii) cardiac morphology, and iii) cardiovascular physiology. Each criterion was further subdivided into "typical" presentations and scored accordingly, with the selected morphologies spanning the breadth of CHD severity. 10 example lesions representing a range of CHD severities, requiring surgical intervention, were then scored based on their "typical" presentation and clinical course to validate the scoring system.

Following development of the comprehensive system, it was tested using real patient data, with three patients for each of the 10 common CHD lesions, reflecting the breadth of CHD severity (n = 30). This analysis required detailed assessment of the comprehensive CHD severity classification system criteria, using patient medical records. Patients were selected at random based on their primary lesion, using the European Paediatric Cardiac Code (EPCC) system and scored against the criteria of the comprehensive CHD classification system, with a total score calculated for each patient.

Development and analysis of the simplified CHD severity system

Informed by findings from the first-tier analysis, we explored options for a simplified version of the classification system using morphology as a stand-alone predictor. We removed the "timing of intervention" and "cardiovascular physiology" criteria, which rely on detailed patient information from the medical record. The simplified version of the CHD severity classification system therefore only requires prior knowledge of the primary lesion, to classify patients according to severity. To test the simplified version of the system, 12 clinicians of differing specialities, involved in the care of children with CHD, ranked 10 selected lesions spanning the breadth of CHD severity from 1 ("least severe") to 10 ("most severe"), based on the typical presentation and anticipated clinical course for each lesion. Clinicians included experienced consultants from a single site, across multiple specialities, including cardiothoracic surgeons, cardiologists (cardiac), neonatologists, and paediatric intensivists (non-cardiac). Specialists were asked to consider the typical presentation and usual course for each CHD lesion and to assume patients were non-syndromic. Independent samples t-tests were used to compare differences between cardiac and non-cardiac clinician responses, using SPSS version 25.

Following second-tier analysis and informed by the morphology scores and ranking system, individual CHD lesions were grouped into broad severity categories: Group A, B, and C. Group A lesions (encompassing lesions with morphology scores of 8–10) comprise more complex cases typically associated with more "severe" disease requiring neonatal bypass operations and ongoing monitoring and care. Group B, lesions (representing morphology scores 3–7), represent those with "moderate" disease, requiring intervention after the neonatal period with ongoing monitoring and care. Finally, Group C lesions (representing morphology scores 1–2) comprise "simpler" disease requiring intervention but typically not requiring ongoing monitoring and discharge from cardiac care.

Results

Tier one analyses identified and confirmed that the main driver for the overall comprehensive score was cardiac morphology (Table 1) and that additional scores attributed to "timing of intervention" and "cardiovascular physiology" largely did not alter the severity ranking. As such, the total scores, encompassing all criteria (including "timing of intervention," "cardiac morphology," and "cardiovascular physiology"), from the example lesions and the morphology scores alone, were ranked in the same order across the severity range (Supplementary Table S1). The analysis incorporating real patient data (Supplementary Table S2) further identified and confirmed morphology as the main driver, with the exception of a patient with AVSD (Patient 2) who experienced significant cyanosis and signs of cardiac failure pre-operatively, resulting in a higher total score.

Overall, the analysis of the comprehensive system, supported cardiac morphology as a stand-alone predictor of severity, with negligible additional variation attributed to "timing of intervention" and "cardiovascular physiology" among real patient data (Supplementary Table S2).

Second-tier analysis of the simplified CHD classification system confirmed the morphology scoring and broad CHD severity groupings across the severity range (Table 2) was generally coherent across assessors. Assessors consisted of five (42%) paediatric cardiologists, two (16%) cardiothoracic surgeons, and five (42%) neonatologists/intensivists. Overall, there was little variation between assessors in lesion rankings at the extreme ends of the severity spectrum, and all specialists agreed on the ranking of the simpler lesions comprising broad CHD severity Group C, that is, atrial and ventricular septal defects (Table 2, Figure 1). However, there was some variation in the ranking of moderate to complex lesions among specialists, particularly among non-cardiac specialists. Specifically, specialists who were from disciplines other than paediatric cardiology and cardiac surgery (non-cardiac specialists) regarded AVSD as more complex than dextro-transposition of the great arteries (cardiac average score = 6.6, non-cardiac average score = 6.0; $p = 0.548$), resulting in AVSD

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Table 1. The comprehensive CHD severity classification and scoring system

Criteria			Score	
Timing of intervention (score highest only)	Requires intervention within 7 days		5	
	Requires intervention within 1 month		4	
	Requires intervention within 1 year		3	
	Requires intervention non-urgently		2	
	Does not require intervention		1	**Broad CHD severity group**
Morphology (score highest only)	Functional single ventricle		10	Group A
	Complex heart disease requiring multiple surgical interventions in early life with or without heterotaxy syndrome (e.g., ccTGA)		9	
	Ventriculoarterial anomaly (dTGA, DORV with significant malposition) and truncus		8	
	TAPVR		8	
	Common AV canal		7	Group B
	Tetralogy of Fallot		7	
	Coarctation of the aorta		6	
	Partial anomalous pulmonary venous drainage		5	
	LVOTO (isolated)		4	
	RVOTO (isolated)		3	
	VSD		2	Group C
	ASD		2	
	PDA after 38 weeks gestation and 1 week of age		1	
Physiology (score for each category)	Shock	Present (resuscitation required)	5	
		Proactively managed	2	
		Not present	0	
	Ductal dependency	Yes	5	
		No	0	
	Shunt size/volume load	None	0	
		Small	2	
		Moderate	4	
		Large	5	
	Cyanosis	None	0	
		Mild (saturation>85%)	2	
		Moderate (saturation 75–85%)	4	
		Severe (saturation<75%)	5	
	Pressure load (suprasystemic)/obstruction (isolated)	None	0	
		Mild (gradient<40 mmHg)	2	
		Moderate (gradient 41–60 mmHg)	4	
		Severe (gradient>60 mmHg)	5	

CcTGA = congenitally corrected transposition of the great arteries, TOF = tetralogy of Fallot, dTGA = dextro-transposition of the great arteries, DORV = double-outlet right ventricle, TAPVR = total anomalous pulmonary venous return, LVOTO = left outflow tract obstruction, RVOTO = right outflow tract obstruction, VSD = ventricular septal defect, ASD = atrial septal defect, PDA = patent ductus arteriosus.

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Table 2. Individual clinician ranking responses to validate the simplified CHD severity system

CHD lesion and morphology score			Clinician ranking of lesions												Average score		
			Cardiac						Non-cardiac								
CHD lesion*	Morphology score	Broad CHD severity groups													All	Cardiac	Non cardiac
HLHS	10	Group A	8	10	10	10	10	10	10	10	10	10	10	10	9.8	9.7	10.0
ccTGA - l-TGA + VSD suitable for anatomic repair	9		10	9	8	9	9	9	7	4	9	6	5	4	7.4	8.7	**5.6**
Truncus arteriosus	8		5	8	9	7	8	8	8	9	8	9	9	9	8.1	7.6	8.8
dTGA	8		7	4	7	8	7	5	6	6	6	5	8	5	6.2	6.3	6.0
AVSD	7	Group B	9	6	5	6	5	7	4	7	4	8	6	8	6.3	6.0	**6.6**
TOF	7		4	4	4	4	4	4	5	5	5	4	3	3	4.1	4.1	4.0
Large perimembranous VSD	2	Group C	3	3	3	2	3	3	3	3	3	3	4	2	2.9	2.9	3.0
Sinus venosus ASD	2		2	2	2	3	2	2	2	2	2	2	2	7	2.5	2.1	3.0
Secundum ASD	2		1	1	1	1	1	1	1	1	1	1	1	1	1.0	1.0	1.0

*In expected ranking order from most to least severe. Scores in bold indicate mismatches in morphology scores and the broad CHD severity groups.
Cardiac lesion abbreviations: ccTGA = congenitally corrected transposition of the great arteries, l-TGA = L-type transposition of the great arteries, TOF = tetralogy of Fallot, dTGA = d-type transposition of the great arteries, DORV = double-outlet right ventricle, TAPVD = total anomalous pulmonary venous return, LVOTO = left outflow tract obstruction, RVOTO = right outflow tract obstruction, VSD = ventricular septal defect, ASD = atrial septal defect.

shifting from Group B to Group A (Table 2, Figure 1). Similarly, congenitally corrected transposition of the great arteries was regarded as significantly less complex by non-cardiac clinicians, compared with cardiac clinicians (cardiac average score = 8.7, non-cardiac average score 5.6; $p = 0.005$), resulting in congenitally corrected transposition of the great arteries moving from Group A to Group B in the broad CHD severity groups (Table 2, Figure 1). This was the only variance in rankings that resulted in a change in the broad CHD severity categories. Cardiac specialists' ranking matched the expected morphology scores and broad CHD severity groups of the CHD severity classification system. (Table 2, Figure 1). Based on the findings from the first- and second-tier analysis, a simplified CHD severity classification system was developed (Table 3).

Discussion

This CHD severity classification system was developed to support our research efforts requiring a simplified classification system for CHD severity, allowing use with limited specialised clinical knowledge and/or restricted access to detailed patient medical records. The two-tiered analysis process permitted a comprehensive review of patients and lesion categories, that gave rise to a simplified version of the tool (Table 3), which is of relevance to non-cardiac clinicians (e.g., psychology, allied health, and nurses) and researchers (e.g., laboratory/genomic, epidemiology, or computational). This is presented as potentially useful for other researchers working in CHD research.

Tier one analysis confirmed the utility of the comprehensive system, and additionally that cardiac morphology is the primary driver of CHD severity, with "timing of intervention" and "cardiovascular physiology" making negligible contributions towards the final severity ranking. The use of real patient data to test the comprehensive system (Supplementary Table S2) supported the "typical" scoring implemented in the development of the system (Supplementary Table S1) and the progression to tier two analysis to assess and confirm the applicability of the "simplified severity system" more broadly among cardiac and non-cardiac specialists. While some minor differences were noted in tier two analysis, the ranking of lesions between cardiac and non-cardiac clinicians, collectively, were in keeping with the proposed classification system and the broad CHD severity groups. The results of the analysis informed and validated the broad CHD severity groups, to assist in classifying CHD severity more broadly in a research capacity (Table 3). However, the broad CHD groups are a guide and may be amended accordingly, and in line with, the specific research question and local management strategies for CHD. The differences noted between cardiac and non-cardiac clinicians most likely reflect the involvement of clinicians with varying roles in, and timing of, care (e.g., at birth vs. at time of surgical repair vs. neonatal intensive care pre-/post-surgery) and variable exposure to lesion types (e.g., some lesions may not commonly present to neonatal ICU). In addition, the outcomes of this stratified classification may not be directly transferrable to every centre or project; however, it does provide details of a process that could be used and adapted to suit local needs.

Overall, these findings support morphology as the key driver of severity classification. In comparison to other CHD severity classification systems, this system is not limited by prior advanced knowledge of, or experience with, CHD nomenclature and associated administrative disease coding, thereby increasing its utility.[5,11] Further, this system enables additional utility for

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Table 3. The simple CHD severity classification and scoring system

CHD lesion	Score	Broad CHD severity group	Specific CHD examples
Functional single ventricle	10	Group A	HLHS, PA/IVS, tricuspid atresia, right atrial isomerism, left atrial isomerism, ccTGA, dTGA, truncus, DORV – transposition type, TAPVR
Complex heart disease requiring multiple surgical interventions in early life with or without heterotaxy syndrome (e.g., ccTGA)	9		
VA anomaly (dTGA, DORV with significant malposition) and truncus	8		
TAPVR	8		
Common AV canal (AVSD)	7	Group B	TOF, AVSD, CoA, DORV – Fallot type, Ebstein anomaly, PAPVR, ALCAPA, sub-aortic membrane, AS (isolated), PS (isolated)
Tetralogy of Fallot	7		
Coarctation of the aorta	6		
Partial anomalous pulmonary venous drainage/return	5		
LVOTO (isolated)	4		
RVOTO (isolated)	3		
VSD	2	Group C	ASD, VSD, isolated DORV, vascular ring
ASD>1 year	2		
PDA after 38 weeks gestation and 1 week of age	1		

HLHS = hypoplastic left heart syndrome, PA/IVS = pulmonary atresia/intact ventricular septum, ccTGA = congenitally corrected transposition of the great arteries, TOF = tetralogy of Fallot, dTGA = dextro-transposition of the great arteries, DORV = double-outlet right ventricle, TAPVR = total anomalous pulmonary venous return, LVOTO = left outflow tract obstruction, RVOTO = right outflow tract obstruction, VSD = ventricular septal defect, ASD = atrial septal defect, PDA = patent ductus arteriosus.

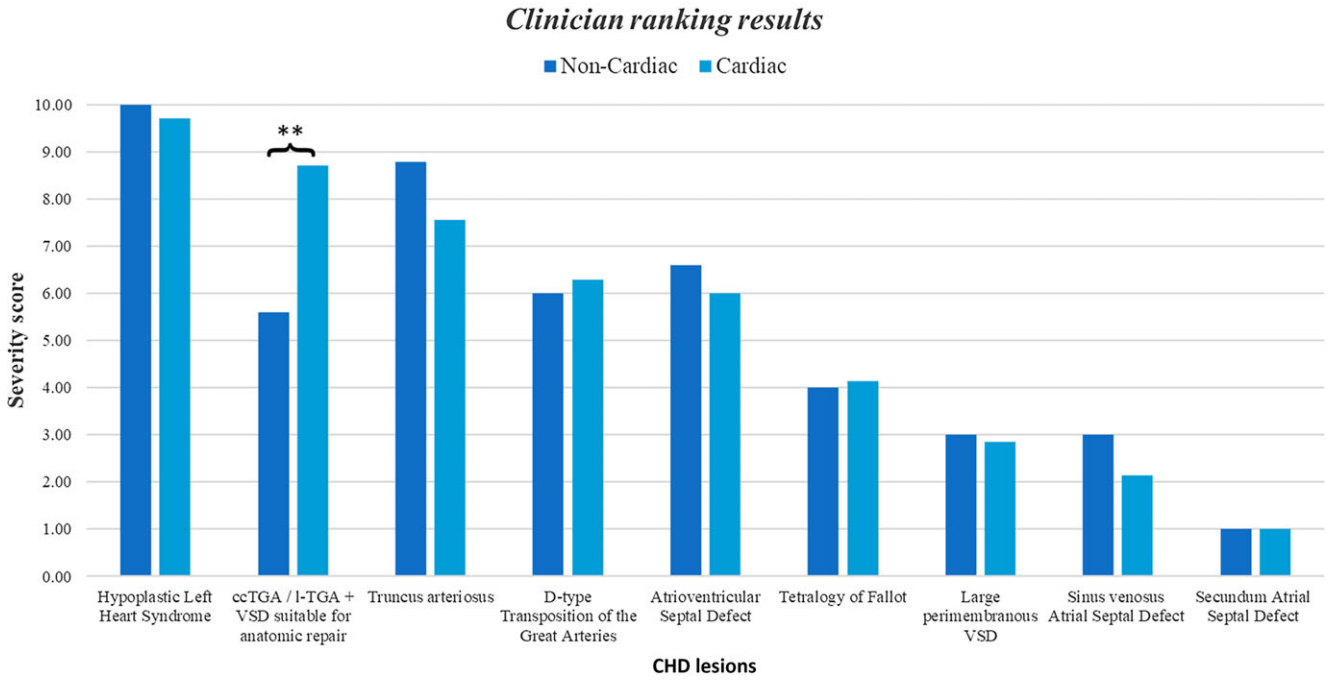

Figure 1. Cardiac and non-cardiac clinician rankings of 10 common CHD lesions from most severe (score = 10) to least severe (score = 1). *Note:* ccTGA = congenitally corrected transposition of the great arteries, l-TGA = L-type transposition of the great arteries, VSD = ventricular septal defect. ** $p < 0.01$ when comparing non-cardiac to cardiac responses.

researchers and clinicians with varying clinical CHD expertise and/or access to patient medical records, in that it offers both a comprehensive and simplified version. Whilst systems have been developed to assess specific factors such as quality of life,[8,12,9] and morbidity and mortality associated with surgical complexity,[7,15] this system does not specifically assess these factors, reducing the data burden for users. Finally, unlike some other systems designed specifically with adult disease in mind, this system was purpose built in the paediatric setting where primary intervention for CHD mostly occurs, but with some applicability across the lifespan. For

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some studies, the more comprehensive first-tier approach may be preferred. Of note, and in comparison, to other systems, this system does not attempt to assess additional outcomes measures such as quality of life, morbidity, fetal outcomes, and clinical surveillance.[5–9,11,17]

Limitations

A range of clinical specialists, including cardiac and non-cardiac, were involved in the development of this system. However, institutional bias relating to treatment and experience cannot be excluded as they all largely practice at a single site. Further, when asked to rank the lesions, it is important to remember that patients vary in clinical course and presentation and recall bias may influence how clinicians ranked specific lesions. As such this system reflects the "typical" clinical presentation and course for each lesion and exclusively uses the primary lesion as the determining factor for severity. This system was developed to be used without expert CHD knowledge and experience, acknowledging that, particularly the simplified version, may not address the level of nuance for fine distinction of a patient population, which would require expert input. The degree to which this can be directly applied internationally will be impacted by social, economic, and medical factors, although the model could be applied to develop locally relevant outcomes.

Conclusion

CHD severity stratification is important for some research studies. We offer a simplified CHD severity classification system that may be of use to research staff without an intimate knowledge of CHD. The development of this system into three broad CHD severity groups are supported by findings of this study. The model may be applied to produce locally relevant research tools.

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Competing interests. None.

Ethical standards. The authors assert that all procedures contributing to this work comply with the ethical standards of the National Statement on Ethical Conduct in Human Research (2018) and with the Helsinki Declaration of 1975, as revised in 2008, and have been approved by the Sydney Children's Hospital Network, Human Research Ethics Committee and Research Governance.

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