

Diagnostic Errors in Congenital Echocardiography: Importance of Study Conditions

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Background: Diagnostic errors are unwanted clinical events that place patients at risk for injury. The authors have previously reported that a majority of congenital echocardiography errors have clinical impacts and, on the basis of a small cohort, identified factors associated with diagnostic error. The objectives of this study were (1) to evaluate patient risk factors for diagnostic errors in a large contemporary cohort and (2) to identify risk factors for situation-related diagnostic errors.

Methods: Diagnostic errors were identified at a large academic pediatric cardiac center from 2004 to 2011. Clinical and situational variables were collected from diagnostic error cases and controls.

Results: Among the 254 diagnostic error cases, 66% affected clinical management or patients experienced adverse events; 77% of errors were preventable or possibly preventable. Coronary arteries, pulmonary veins, and the aortic arch were most commonly involved with diagnostic errors. Multivariate analysis identified the following patient-related risk factors: rare or very rare diagnoses (adjusted odds ratio [AOR], 6.3; $P < .001$), high anatomic complexity (AOR, 3.4; $P < .001$), and weight < 5 kg (AOR, 2.7; $P < .001$). Risk factors related to the setting of the echocardiographic study included evening or night (7 PM to 6:59 AM) study interpretation (AOR, 2.6; $P = .005$) and weekend studies (Friday through Sunday) (AOR, 1.6; $P = .04$). The model area under the receiver operating characteristic curve was 0.833.

Conclusions: In addition to patient risk factors, the setting of an echocardiographic study and interpretation contribute to risk for a diagnostic error. Studies interpreted overnight or performed during a weekend should be considered for a quality improvement activity to reduce diagnostic errors or their impact. (*J Am Soc Echocardiogr* 2014; ■: ■-■.)

Keywords: Congenital echocardiography, Diagnostic error, Quality, Outcomes

Diagnostic errors are unwanted clinical events that place patients at risk for injury and are a leading cause of malpractice claims.^{1,2} Echocardiography is the first line of diagnostic investigation among patients suspected of having congenital heart disease,^{3,4} and diagnostic errors may place patients at risk for suboptimal outcomes.^{5,6} We have previously reported that a majority of congenital echocardiographic diagnostic errors have clinical impacts.⁵ That analysis, however, was based on a relatively small cohort. Using a large contemporary cohort, the objectives of the present study were (1) to determine patient-related risk factors for diagnostic errors and (2) to identify independent risk factors related to the situation in which echocardiographic studies are performed and interpreted.

Situational risk factors may be responsive to quality improvement strategies to reduce diagnostic errors or to mitigate their impact.

METHODS

The Scientific Review Committee of the Department of Cardiology and the Institutional Review Board at Boston Children's Hospital approved this study. The authors had full access to and take full responsibility for the integrity of the data. All authors have read and agree to the report as written.

Data Source

The Echocardiography Laboratory at Boston Children's Hospital performs approximately 22,000 echocardiographic studies annually. These studies are performed in locations such as echocardiography suites, satellite cardiology clinics, operating rooms, intensive care units, recovery rooms, catheterization laboratories, cardiology wards, emergency departments, and general pediatric wards. Trained pediatric and congenital sonographers, cardiology fellows, and echocardiography staff cardiologists perform the examinations. The cardiac sonographers are provided with a requisition to perform a study, and they review the requisition and study questions before performing the study. Before study completion, the sonographer will discuss the pertinent findings with the noninvasive cardiologist.

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Abbreviations

AOR = Adjusted odds ratio

CI = Confidence interval

ologist after the interpretation of the echocardiogram was the outcome of interest in this study; preliminary results reported by cardiac sonographers or trainees were not examined. Postnatal pediatric and congenital echocardiograms were the subject of this study.

Diagnostic Error Case Ascertainment

Between December 2004 and March 2011, as part of a continuous quality improvement initiative in the Noninvasive Cardiology Division, data related to diagnostic error cases were collected prospectively through voluntary reporting and active quality assurance mechanisms. We have previously reported these methods.⁵ A diagnostic error was defined as a diagnosis that was unintentionally delayed, wrong, or missed as judged from eventual appreciation of the existing data or more definitive information.⁵ The sources of diagnostic error case discovery included information obtained from other tests (e.g., cardiac catheterization, magnetic resonance imaging), operative observations, subsequent echocardiographic examinations, and autopsy.

Data Collected

The following patient demographic and case data were collected: age, referral diagnosis, weight, race, prematurity, anatomy involved in diagnostic error, and study indication or question. Other data obtained included study location, use of sedation or anesthesia, comments on image quality, day of week, and time of day the study was performed and interpreted. Data related to the number of interim studies or procedures performed before the diagnostic error discovery was also noted, including the method of discovery.

Diagnostic frequency, defined as the frequency a diagnosis is encountered in the echocardiography laboratory, was categorized as follows: (1) frequent (diagnosis is observed more than once per week; e.g., patent ductus arteriosus), (2) intermediate frequency (diagnosis is observed more than once a month but less than once weekly; e.g., coarctation of the aorta), (3) rare (diagnosis is observed more than once per year but less than once monthly; e.g., inferior-type sinus venosus defect), and (4) very rare (diagnosis is observed less than once yearly; e.g., aortic–left ventricular tunnel).

Anatomic complexity data were divided into 3 categories: (1) low (no significant heart disease or a single, simple structural cardiovascular anomaly; e.g., atrial septal defect or single membranous ventricular septal defect), (2) moderate (abnormalities involving more than one cardiovascular structure or diagnoses with moderately common characteristics; e.g., complete common atrioventricular canal, hypoplastic left heart syndrome, transposition of the great arteries), and (3) high (uncommon variants of moderately complex anatomic diagnoses or rare, complex anomalies; e.g., dextrocardia, superior-inferior ventricles with crisscross atrioventricular relations, hypoplastic right ventricle, and straddling mitral valve).⁷

Diagnostic Error Case Review Process

Staff echocardiographers reviewed diagnostic error cases and other diagnostic data in addition to the images of the studies in question, as previously described⁵ (Figure 1). Briefly, diagnostic error cases

The echocardiography staff cardiologists interpret all studies and issue reports, which are stored in the hospital's electronic medical records. The final diagnosis reported by the staff cardiologist

were reviewed by staff pediatric echocardiographers, including review of medical records and other diagnostic images in addition to the images of the studies in question. Interviews with sonographers, trainees, cardiologists, and other involved health care providers were conducted to understand the conditions and the context in which the examinations were performed and interpreted, to determine the clinical impact, and to identify primary causes of the diagnostic errors.

The relevant clinical and image data were presented at a monthly noninvasive morbidity and mortality conference. This process involves a systematic review of the echocardiographic process to identify contributors to the diagnostic error in question. Case discussion included categorization of diagnostic error type, severity, preventability, and contributors or root causes. Participants in the conference include attending physicians, trainees, and cardiac sonographers from the noninvasive division, as well representatives from other divisions within the Department of Cardiology and other disciplines (e.g., cardiac anesthesia and cardiovascular surgery). A consensus based on a review of the case and the ensuing discussion was used to finalize categorization of the diagnostic error type, severity, preventability, and root cause.

Definitions and Classification of Diagnostic Errors

A diagnostic error was defined as a diagnosis that was unintentionally delayed, wrong, or missed, as judged from eventual appreciation of the existing data or of more definitive information.⁸

Diagnostic Error Categorization. False-negative: An error that omits a finding or states that a finding is normal (or absent) when an abnormality is present, or the reader failed to include a significant diagnostic possibility (e.g., patent ductus arteriosus is ruled out or omitted when it is evident on the study images).

False-positive: An error that reports an abnormality but no abnormality is present, or the reader overemphasized the significance of a finding (e.g., atrial septal defect is diagnosed when the atrial septum is intact).

Discrepant diagnosis: The actual diagnosis is different from the one made (e.g., diagnosis of double-inlet left ventricle is made when the actual diagnosis is tricuspid atresia).

Severity Categorization. Diagnostic errors were categorized by severity into the following categories on the basis of clinical impact: minor, moderate, severe, and catastrophic (Table 1).

Minor: A diagnostic error or discrepancy that does not change patient management or affect clinical course, with little or no potential for adverse event (e.g., missed left superior vena cava to an intact coronary sinus in a patient with an otherwise structurally normal heart).

Moderate: A diagnostic error or discrepancy with an impact on management, whereby the patient may be placed at risk and/or experience a transient adverse event (e.g., missed primum atrial septal defect in an infant).

Major: Diagnostic error discrepancy with impact on management that results in an adverse event, including the performance of unnecessary invasive procedure, or a long-lasting or permanent adverse event (e.g., false-positive diagnosis of an atrial septal defect leading to an unnecessary surgery to close a defect that was not present).

Catastrophic: A diagnostic error or discrepancy that contributed to patient death (e.g., missed anomalous coronary artery from

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