Original Article

Audit of pulse oximetry screening for critical congenital heart disease (CCHD) in newborns

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Abstract

Objectives: To assess the efficacy of a new screening protocol for critical congenital heart disease (CCHD).

Background: In March 2014, the Ontario Provincial Council for Maternal Child Health (PCMCH) recommended screening for CCHD, utilizing pulse oximetry to measure oxygen saturation as part of the newborn examination. However, this is yet to be implemented in all hospitals.

Method: An audit of consecutive healthy normal newborn patients in a secondary level centre in Ontario with early adoption of the screening recommendation over a 1-year period was undertaken.

Results: The median age of screening was 25 hours (6 to 80 hours). Compliance was 88% (95% if one excludes deliveries by a midwife as they did not agree to comply). Four patients screened positive and were seen by a paediatrician in consultation but did not have CCHD (specificity 99.4%).

Conclusions: The current study shows that screening was successfully implemented in a Canadian hospital, with high specificity (99.4%) and good compliance (88%). Reasons for non-acceptance of screening by midwives need to be addressed.

Keywords: *Critical congenital heart disease; Screening.*

BACKGROUND

Congenital heart disease occurs in 9 of every 1000 live births (1) of which approximately 25% have critical congenital heart disease (CCHD) (1). Data from the UK suggests that 25% of infants with CCHD were not diagnosed until after discharge (0.6 per 1000) (1).

The majority of infants with CCHD present with some degree of hypoxemia in the newborn period which can be detected by routine pulse oximetry (1). The 2011 American Academy of Pediatrics working group (2) identified seven specific lesions targeted for screening: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus. A 2012 working group further defined areas of concern including equipment selection, reporting standards and training of health care providers (3).

The direct and indirect costs of pulse oximetry (with the greatest cost being staff time) need to be weighed against the cost of missed diagnosis (1). A population-based study in China studied 120,707 asymptomatic newborns (2014). Pulse oximetry detected 84% of asymptomatic cases of CCHD, and when clinical assessment was added in the sensitivity rate improved to 93.2%. The false positive rate for detection of CCHD was 0.3%, with a specificity rate of 99.7% (4).

However, a US tertiary level hospital study found that routine pulse oximetry screening performed on 6838 infants did not detect any new CCHD cases because of effective prenatal echocardiography screening (5). It is not clear if prenatal echocardiographic screening is sufficiently utilized in Canada to obviate the utility of routine pulse oximetry screening in the newborn.

In March 2014, the Maternal Child Newborn Screening Committee of the Provincial Council for Maternal Child Health (PCMCH) recommended that pulse oximetry screening be added to the panel of routine newborn screening for all infants born in Ontario. At the time of submission of this report, this recommendation has not yet been operationalized throughout Ontario. The purpose of this study is to report initial results from one hospital.

METHODS

In 2014, a protocol was instituted at Orillia Soldiers Memorial Hospital (OSMH) requiring that all asymptomatic infants ≥ 37 weeks gestation have an oximetry reading done prior to discharge (ideally over 24 hours of age unless discharged earlier). The infant failed screening if oxygen saturation was less than 90%, saturation was less than 95% in right hand and foot on three repeated measures, each separated by 1 hour, or a greater

than 3% difference in oxygen saturation measurement between the right hand and foot on three repeated measures, each separated by 1 hour. Consultation with a paediatrician was encouraged for infants with failed screening tests (6).

Data on screening results were collected for April 1, 2014 to March 31, 2015 including age at time of screen, nurse/midwife performing the screen, inpatient/outpatient at time of screen, positive screen (Y/N/unknown), disposition of positive screen patients, number of false positives requiring further evaluation and number of false negatives (assuming that any infants with missed CCHD would be known to our paediatric group).

Sensitivity, specificity and compliance were assessed. Ethics approval was obtained from OSMH.

RESULTS

For the 1-year audit period, 964 births were recorded. Of these, 61 were not screened because they received midwifery care and the midwives did not agree to the screening program, 138 were not screened because they were premature or required specialized care and 41 were missed. The overall compliance rate (excluding those in the premature group) was 88%. When the midwife cases were excluded, as they did not agree to the screening program, the rate was 95%.

Those screened had a median age of 25 hours (range 6 to 80 hours). Four of the 724 patients who were screened failed; all were seen by a paediatrician, none were referred for an echocardiogram or had CCHD. The specificity of this test therefore was 99.4% (care should be taken in interpreting this number, as the number of positive tests is less than 5). The sensitivity of the test cannot be determined as there were no cases of CCHD (of note, no cases of CCHD occurred between the end of the study on March 31, 2015 and September 15, 2016).

DISCUSSION

Newborns with CCHD are susceptible to profound sudden worsening in clinical status in the first days and weeks of life. The most important long-term effects are associated with brain injury from ischemia and subsequent reperfusion. Importantly, deaths related to delayed diagnosis range from 1 to 2 per 100,000 live births (1).

The US experience (2013) indicates screening is estimated to save 20 infant lives annually at a cost of \$40,385 per life year gained under base case assumptions. Costs including echocardiography were estimated at \$6.66 per screening newborn (7).

CONCLUSION

The current study shows that pulse oximetry screening was successfully implemented in a Canadian hospital, with high specificity (99.4%) and good compliance (88%). Reasons for rejection of the recommendations to screen by midwives need to be addressed. Much larger studies will be required to determine the utility of screening in Canada.

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