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Learning curve for lung area to head circumference ratio measurement in fetuses with congenital diaphragmatic hernia

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ABSTRACT

Objective *To assess the learning curve for the fetal lung area to head circumference ratio (LHR) calculation in fetuses with congenital diaphragmatic hernia (CDH).*

Methods *Three trainees with the theoretical knowledge, but without prior experience in the LHR measurement, were selected. Each trainee and one experienced examiner measured the observed to expected (O/E)-LHR in the lung contralateral to the side of the hernia by two methods – manual tracing of lung borders and multiplication of the longest diameters – in a cohort of 95 consecutive CDH fetuses. The average difference between the three trainees and the expert in the O/E-LHR measurement was calculated. A difference below 10% was considered to indicate an accurate measurement. The average learning curve was delineated using cumulative sum analysis (CUSUM).*

Results *The CUSUM plots demonstrate that the learning curve was achieved by 77 and 72 tests performed for the area obtained by the manual-tracing and multiplication-of-the-longest-diameter methods, respectively.*

Conclusion *The minimum number of scans required for an inexperienced trainee to become competent in examining the LHR is on average 70. Copyright © 2010 ISUOG. Published by John Wiley & Sons, Ltd.*

INTRODUCTION

Congenital diaphragmatic hernia is associated with a high postnatal mortality rate owing to pulmonary hypoplasia[1]. Lung area to head circumference ratio (LHR) measured by ultrasonography provides prediction of postnatal survival, with an improvement in postnatal survival with increasing prenatal values[2,3]. However, the reported results on LHR performance lack consistency, probably because of different criteria being used for patient selection and different methodologies being used in the estimation of the lung area[4–8]. Recently, it has been reported that area tracing rather than diameter-derived area is a more reliable parameter[9]. Furthermore, the LHR changes with changes in gestational age and fetal size, increasing the variability of this estimation[10,11]. Attempts to account for this variability have been made by adjusting the observed LHR against that expected for gestational age, in the observed to expected LHR ratio (O/E-LHR). Clinical studies suggest that O/E-LHR yields more accurate prediction of pulmonary hypoplasia[12,13]. LHR is a demanding measurement owing to the difficult delineation of the borders of the lung in relation to its surrounding tissues, and concerns exist as to whether the operator's competence could have influenced the results of some published studies[8]. No previous paper has evaluated the learning curve of these parameters in order to set the minimum number of cases required for an operator to yield reliable measurements.

Cumulative sum (CUSUM) analysis is a graphic method that has been used for quality control in monitoring doctors' performance on a case-by-case basis, showing changes in competence over time[14–17] and to assess learning curves of trainees in different diagnostic methods and surgical operations as well as fetal ultrasound measurements[18–21].

The aim of this study was to determine the number of ultrasound examinations that are necessary for an inexperienced sonographer to perform in order to achieve competence in performing the O/E-LHR measurement in fetuses with isolated congenital diaphragmatic hernia (CDH).

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METHODS

Subjects

Three fetal medicine fellows with more than 1 year of experience in ultrasonography but who had never previously measured the LHR in fetuses with CDH were instructed on this measurement by one experienced operator (E.G. or J.M.M.) by means of offline video clips. Between October 2005 and February 2009, 95 consecutive fetuses with isolated CDH referred to our hospital for CDH were included. In order to estimate the O/E-LHR in each case, the head circumference was measured by one experienced examiner and the lung area was then estimated firstly by the experienced examiner and secondly by each of the trainees, blinded to previous measurements. The average difference between the three trainees and the expert in the O/E-LHR measurement was calculated. The measurements were considered accurate when the individual measurements, or the mean value of the three trainees when considered together, were less than 10% different from the expert measurement. When the difference, or the mean difference, was $\geq 10\%$ it was considered a failure. Similarly, lack of success in obtaining the required ultrasound plane was also considered for the analysis as a failure, with the mean of the remaining two trainees used for the group analysis in such cases. This study was approved by the hospital ethics committee, and patients provided written informed consent.

Lung to head ratio measurements

Fetal ultrasound examinations were performed using a Siemens Sonoline Antares (Siemens Medical Systems, Malvern, PA, USA) ultrasound machine equipped with a 6–2-MHz linear curved-array transducer. The lung contralateral to the side of the hernia was evaluated in a cross-sectional view of the fetal thorax at the level of the cardiac four-chamber view. The LHR was estimated firstly by multiplication of the longest diameter by its widest perpendicular diameter and secondly by manual tracing of the lung borders as described previously[11,22]. The expected LHR values were calculated using normal reference ranges according to gestational age and the side of the hernia for both the longest-diameter and the tracing methods[11,13]. The observed LHR value was compared with the expected LHR in order to calculate the O/E-LHR as (LHR observed/LHR expected) × 100. Only one set of measurements for each patient was included in the analysis.

Statistical analysis

CUSUM analysis was performed for each of the two methods of lung area estimation, and for each component measurement of the longest diameter method, according to published standard methodology[14–21], using Excel for Windows 2007 (Microsoft Corp., Redmond, WA, USA) statistical software. CUSUM charts were generated both for each individual trainee and for their averaged measurements. In short, the CUSUM values are plotted on the y-axis and the number of examinations on the x-axis. Horizontal lines are plotted at regular intervals on the y-axis, defining h0 and h1 for the spacing between unacceptable and acceptable boundary lines, respectively. The CUSUM graph is the running sum of a series of increments (with each failure) and decrements (with each success). When the number of failures exceeds the unacceptable failure rate or is lower than the acceptable failure rate, the graph shows a positive or a negative slope, respectively. The acceptable and unacceptable failure rates were set at 10% (i.e. $p_0 = 0.1$) and 25% ($p_1 = 0.25$), respectively, and Type 1 (α) and Type 2 (β) error rates were set at 0.1. According to the standard formulae, the decrement with each success was calculated as (s) = Q/(P+Q) $= 0.18/(0.92 + 0.18) = 0.17$, the increment of each failure as $(1 - s) = 1 - 0.17 = 0.83$, and the spacing between the unacceptable (h0) and the acceptable (h1) boundaries as $a/(P+Q) = 2.2/(0.92 + 0.18) = 2^{15}$, where $P = \ln(p_1/p_0)$, $Q = \ln((1 - p_0)/(1 - p_1))$, and $a = \ln((1 - \beta)/\alpha)$. This means that for each failure the line will go up by 0.83 units and for each success it will go down by 0.17, with competence declared when the plot falls below the lower boundary of h_1, i.e. dropping below two consecutive boundary lines[17].

RESULTS

Among the 95 included cases, 80 had left-sided CDH and 15 right-sided CDH. In 71 (74.7%) cases there was intrathoracic herniation of the liver. Mean gestational age at evaluation was 30.3 ± 4.3 weeks. The O/E-LHR as measured by the experienced examiner was less than 26% in 25 (26.3%), 26–30% in 18 (18.9%), 30–45% in 28 (29.5%) and above 45% in 24 (25.3%) fetuses.

Among the total 285 O/E-LHR measurements performed by the three trainees, the number of failed examinations ($\geq 10\%$ difference with the experienced operator) was 38 (40.0%) and 41 (43.2%) for the manual-tracing and the two-longest-diameters methods, respectively, and 32 (33.7%) and 40 (42.1) for the measurement of the longest and widest diameters, respectively. These include 13 failures to obtain an adequate image owing to the fetal position.

The CUSUM plots obtained using the average measurements of the trainees demonstrated that with the manual tracing method competence was achieved by 77 cases performed (Figure 1a), and with the two-longest-diameters approach it required 72 cases (Figure 1b). The CUSUM plot was also delineated for each component of the two-longest-diameters method. The number of attempts of the learning curve was slightly lower for the longest (Figure 1c) than for the widest diameter (Figure 1d) (84 vs. 96, respectively). Similar findings were observed when individual CUSUM charts were generated for each of the trainees.

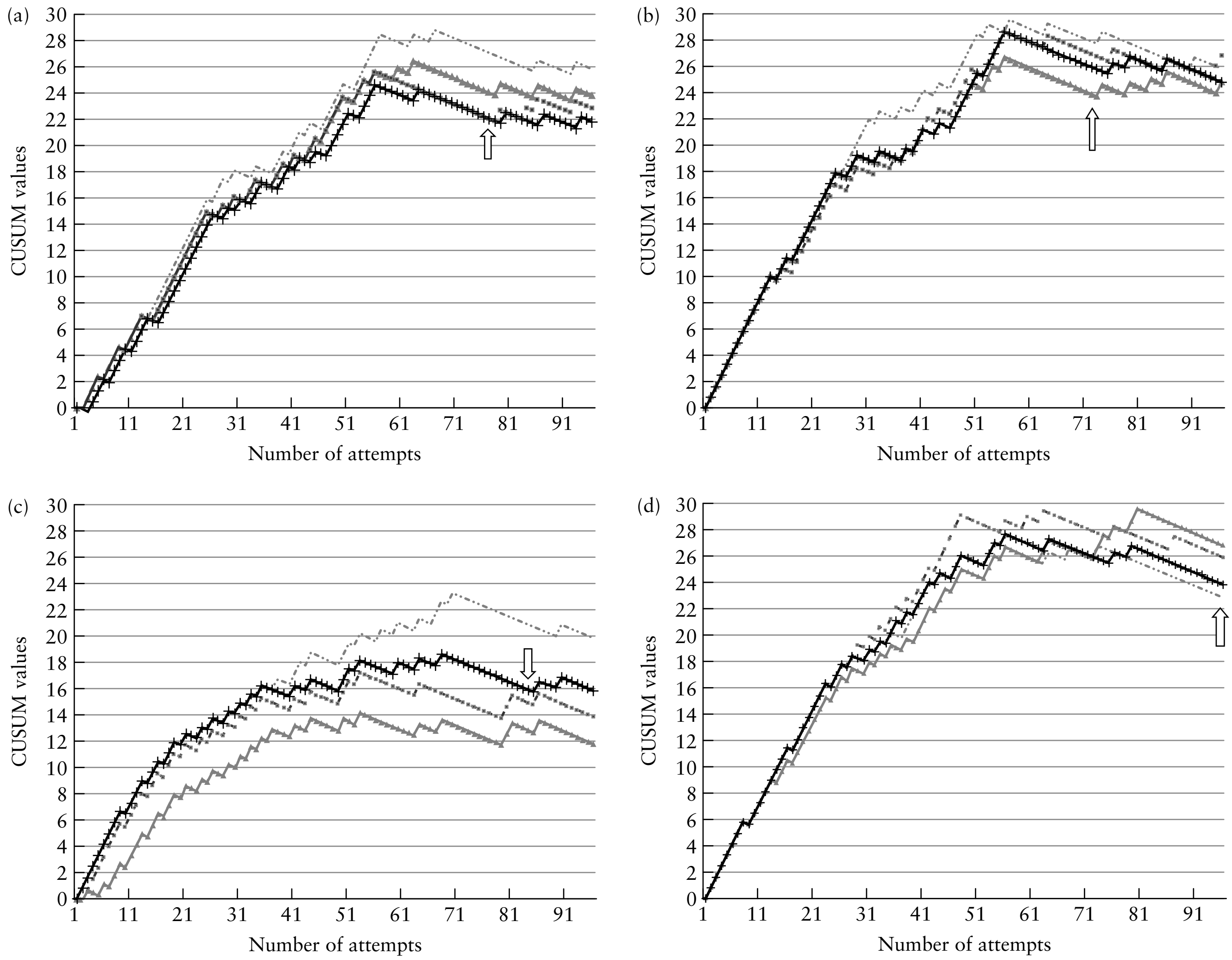

Figure 1 Cumulative sum (CUSUM) graphs of the observed to expected lung area to head circumference ratio, measured by the manual tracing method (a) and the longest diameter approach (b), and of measurements of the pulmonary longest diameter (c) and the pulmonary widest diameter (d). The black graph in each chart shows the CUSUM graph of the average measurement of the three trainees, with the arrows indicating the number of attempts necessary to achieve statistically significant competence. The gray graphs show the individual CUSUM charts of the three trainees. Horizontal lines show acceptable/unacceptable boundary lines of the CUSUM score.

DISCUSSION

This study evaluated the experience required to achieve an acceptable competence on measuring the O/E-LHR. Our findings suggest that to obtain a reliable calculation of the O/E-LHR requires considerable experience. Differences in operators' competence might contribute to explaining the variability among studies and controversies observed in the literature[2–8]. Our findings are consistent with the notion that some fetal ultrasound measurements require formal training before achieving competence and comparability between observers[23–25]. In addition, taking into account the rarity of this disease and the number of scans necessary to achieve competence, this training must be performed in referral units with experience in order to accelerate the learning process.

In this study, the *a priori* acceptable rate of disagreement $> 10\%$ between two competent examiners was set at 10% and the unacceptable rate was set at 25%; as O/E-LHR is a percentage with a mean of around 30% in our population, the 10% limit would mean a variability of $\pm 3\%$ in absolute values. The CUSUM analysis demonstrated that the number of scans necessary to achieve competence under these requirements was similar between the two methods evaluated, tracing and two-diameters measurement. This finding is in line with the clinical observation that one of the main challenges in the calculation of LHR in CDH is to obtain a cross-sectional view of the fetal thorax in a reproducible fashion. While the LHR is supposed to be measured in a four-chamber view of the heart, this view is not easy to obtain because the heart has usually lost its horizontal normal disposition. Another interesting finding is that the transverse lung diameter required a higher number of ultrasound examinations than the longitudinal diameter to achieve competence. To estimate the limits of the lung tissue at the time of calculating the transverse diameter can also be challenging, and care must be taken not to include other viscera, such as the spleen, which in very severe cases is located very close to the contralateral lung.

CUSUM analysis has been used in several studies as a quality control procedure to continuously monitor doctors' performance among different specialties[16] and in assessing imaging processes in fetal medicine, such as biometric measurements[17]. Clinical studies[20,21] have demonstrated that CUSUM analysis is a useful tool for quantifying the duration of a training regimen, providing an early indication of performance as well as individual difficulties or failure to achieve competence. The method is practical, simple to apply, easy to introduce and has proved popular with trainees in some medical and surgical specialties[19,26]. This method determines whether trainees have reached the acceptable predefined level of performance.

The strength of this study is that each operator was blinded to other measurements and they were also blinded to their performance until the end of the study. In addition, each individual component of the O/E-LHR and two different methods of calculation were addressed. However, the study also has some limitations. Firstly, it could be argued that both the expert and the trainees were not representative of their respective populations. Secondly, the head circumference was only estimated by the experienced examiner. It could be argued that our LHR learning curve neglected this component but we recognize that, as the trainees had 1 year's experience with ultrasonography at the beginning of the study, the impact of head circumference measurement on the LHR learning curve could only be marginal. Thirdly, although estimation of the LHR is likely to be more demanding in cases with right-sided CDH and those with herniation of the liver, sample size was limited and did not allow the construction of a learning curve for these subgroups. In addition, the study design did not allow monitoring the competence once acquired and, therefore, loss of competence could not be evaluated.

In conclusion, this study provides evidence that the O/E-LHR estimation requires a substantial number of measurements for a non-experienced examiner to achieve competence. Studies on CDH where O/E-LHR is used should report on the experience of the observers to facilitate comparability of studies.

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