ACCURACY OF PULSE OXIMETRY FOR EARLY DETECTION OF CRITICAL CONGENITAL HEART DISEASE IN VOLGOGRAD REGION (RUSSIA)

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ABSTRACT — A retrospective diagnostic trial for early detection of critical congenital heart diseases (CCHD) was conducted in asymptomatic newborn infants with employment of a pulse oximetry screening (POS) regional protocol. The sensitivity of POS for CCHD detection was 75%, the specificity — 99.9%, the diagnostic test efficiency — 99.9%.

KEYWORDS — pulse oximetry screening (POS), critical congenital heart disease (CCHD), newborns.

INTRODUCTION

The preservation and promotion of children's health is one of the most pressing problems of world health. The solution of this problem has a high social significance and is among the priority tasks, since the health of the younger generation is the fundamental basis for the formation of the reproductive and labor potential of any state [1–5]. Early detection of CCHD improves patient outcomes in relation to both morbidity and mortality. Key screening tests for CCHD identification include prenatal ultrasonography and postnatal clinical examination of neonates. Although, both of these methods are available, CCHD is not detected in a significant proportion of children. Infants with cardiovascular malformations are usually asymptomatic at birth and some of them were recognized in 25% of living infants after discharge [10]. Currently, measuring the difference in blood oxygen saturation (SpO_2) in zones of blood supply above and below the open arterial duct has been proposed for early diagnosis of asymptomatic CCHD. The POS is approved and recommended to CCHD detection in Europe and USA [7]. A systematic review of 21 RCTs (n = 457202) showed high specificity and moderate sensitivity of the POS method for screening diagnosis of CCHD with a very low false positive rate [8]. The

screening in study performed by Hamilçikan Ş., & Can E. (2018) identified infants with other important pathologies, this forms an added value as an assessment tool for newborn infants [6]. Pulse oximetry is highly specific for detection of critical congenital heart defects with moderate sensitivity, that meets criteria for universal screening [9].

Purpose of the study

was to evaluate the POS regional protocol diagnostic capacity as a screening method for CCHD identification in asymptomatic newborns.

METHODS

The design of our retrospective diagnostic trial was approved by the Local Ethic Committee. Parents of enrolling children signed special ICF before any diagnostic procedure. POS regional protocol manipulations were performed in 86,8% (20,527/23,651) newborns from January to December 2017 in 13 obstetric hospitals in the Volgograd region. The gestational age of children were from 34 to 42 weeks (Me 37 (35–40) weeks). In accordance with the regional protocol, POS was measured at 24–48 hours of life in all children on their right arm and any leg, during at least 3 minutes (if no artefacts). Positive POS test criteria's followed by echo-cardiography (ECHO-CG) and cardiac surgeon consultation were: a) SpO_2 <90% on the right arm and/or any leg, b) SpO_2 = 90% or <95% on the right arm and/or leg or c) (SpO_2arm – SpO_2leg) gradient > 3%.

RESULTS AND DISCUSSION

509 cases of congenital heart disease (2,2% of live births) were identified: antenatally —124 (20,3%), postnatally — 385 (79,7%). All cases of congenital heart diseases were symptomatic.

6 positive POS results (0,03%) were reported in asymptomatic group of newborns (N=20527). There were next CCHD: transpositions of the main arteries (N=2), aortic coarctation (N=2), pulmonary artery atresia with intact interventricular septum (N=1) and tetralogy of Fallot (N=1). False negative POS results were obtained in 2 cases (0,01%) — interruption of the aortic arch and aortic coarctation, which is consistent with the data of several authors indicating a low specificity of POS for these types of CHD [5]. False

positive POS results were in 12 cases (0,06%). The sensitivity of POS for CCHD detection was 75%, the specificity — 99.9%, the diagnostic test efficiency — 99.9%.

Our results do not conflict with the results of Plana M. N. et all (Cochrane Systematic Review, 2017), which conclude that pulse oximetry (N=457,202 participants) is a highly specific (99,9%) and a moderately sensitive (76,3%) test for detection of CCHD with very low false-positive rates (0,14%). The current evidence supports the introduction of routine screening for CCHD in asymptomatic newborns before discharge from a well-baby nursery.

CONCLUSION

The regional program of pulse oximetry neonatal screening has shown itself to be a useful method for early detection of CCHD. At the same time, we have to use POS protocol standardization, as well as clinical examination of newborns to ensure diagnostic accuracy of pulse oximetry screening.

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