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NEW DIAGNOSTIC CAPABILITIES OF A RUSSIAN-MADE ANTENATAL FETAL MONITOR

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Objective. *To evaluate the informative value of a Russian-made fully automated and computerized antenatal fetal monitor that has no analogues.*

Material and methods. *The health status of 792 normally developing fetuses in the second half of pregnancy and 26 fetuses born with hypoxia of different severity confirmed after birth was analyzed in detail.*

Results. *It was found during the investigation that cardiotocography showed an erroneous result in 5 of the 792 healthy fetuses. An erroneous result was noted in 1 of the 26 fetuses born with hypoxia of different severity. The fetal functional status could be diagnosed correctly in a total of 812 (99.3%) out of the 818 surveyed fetuses.*

Conclusion. *The main distinctive advantages of this monitor are the following: 1. Full automation of obtained data. 2. The high accuracy of fetal functional status evaluation, which approaches 100% (99.3%). 3. The possibility of monitor curve recording at 22-25 weeks gestation. 4. Automatic estimation of the survey length. 5. The minimum time of an examination is 2 minutes; that of clinical practice is 10 minutes. 6. The possibility of evaluating the fetal status with complete loss of a cardiosignal on the basis of its motor activity analysis.*

Keywords: *antenatal fetal monitor, computer analysis, cardiotocography (CTG), hypoxia.*

Reduction of perinatal mortality is one of the most important issues of healthcare. Therefore, the efforts of the majority of developed countries are aimed at solving this issue. The introduction of various functional methods of investigation into clinical practice in the 60s-90s of the last century led to the reduction of perinatal mortality by 3.5-5 times in developed countries. This was mainly achieved due to the extensive use of the cardiotocography method (CTG) [1].

However, as clinical observations show, the rate of perinatal mortality has somehow recently stabilized, and when it reduced, this was mainly (by 40%) due to the significant improvement in the management of newborns [2, 3].

Data from the literature indicate that at present the main cause of perinatal mortality is acute and chronic fetal hypoxia during pregnancy and delivery, which accounts for 40-70% of perinatal losses [4–7]. It should be kept in mind that the adverse effect of hypoxia is not limited to perinatal mortality, but in 60-80% of cases it leads to dysfunction of various organs and body systems [8].

One of the main signs of these dysfunctions is fetal intrauterine growth restriction, which, according to different authors [9-11], varies between 4.1-8%. It was found that in 32.5% of children born in the state of hypotrophy, physical development abnormalities persisted up to one year [12]. One child in three had the weigh deficit during this period ranging from 500 to 2000 g [13, 14]. In addition, it was also noted that

children with low anthropometric measurements in the first year of life often (in 59%) showed physical and psychomotor retardation (in 31%) [15]. One of the studies [10] found that the weight deficit (within 8−12%) in 39% of children persisted until the end of the second year of life.

In addition to physical retardation of children who had chronic hypoxia due to impairment of immunological status, there was also a tendency to an increased incidence of acute respiratory and intestinal infections, pneumonia, exudative diathesis, anemia and rickets. In 45% of cases there was a later teething, and the number of teeth by the end of the first year of life was by 29.4% less than normal [16].

N.A. Zhernovaya and M.M Melnikova [17] after a long study of the effect of hypoxia on the development of children concluded that their physical and sexual maturation was quite different between the ages of 10 and 17. They often demonstrated various skeletal disproportions, growth retardation, changes in pelvic size, and significant deviations in the development of the reproductive system. In addition to the disorder of sequence of secondary sexual characteristics development, their intensity was impaired, too. The rate of menstrual dysfunction among girls was more frequent than in the population.

Therefore, considering the great clinical importance of the modern and accurate diagnosis of fetal hypoxia, in this paper we decided to present our first results on the

effectiveness of using fully automated and computerized antenatal fetal monitor of the latest generation, developed by Unicos, Moscow.

Material and methods

In this investigation 818 women in the third trimester of pregnancy were assessed. The gestation age at the time of the assessment ranged from 25 to 41 weeks. 274 (33.5%) patients were first-time mothers. 482 women (55.1%) had vaginal deliveries. 435 (40.9%) patients underwent Cesarean section, of which 414 (94.9%) were caused by the mother's condition and only 21 (5.1%) – by the fetus condition. Full-time birth occurred in 713 (87.1%) of pregnant women and the birth was premature at 30-36 weeks of gestation in 104 patients.

It should be noted that this investigation included only the analyzed data of women who had a fetal impairment not associated with the pathological process of delivery, and the time interval from the time of the investigation to the time of delivery did not exceed 5 days.

At the one minute Apgar, there were 790 children with a score of 8-10 points, 11 newborns scored 7 points, 11 newborns had 5-6 points, 2 newborns scored 4 and 2 points, and 2 newborns died antenatally.

In addition, the weight and height of a newborn, as well as his/her general condition, motor activity, muscle tone, time of breastfeeding attachment, tremor, acrocyanosis, signs of functional and morphological immaturity, and laboratory data were also taken into account. In 9 children who were born in a state of hypoxia, the gas composition of blood was assessed. The weight of the newborns ranged from 1891 g to 4451 g. Hypotrophy of various intensities was established in 12 newborns.

Depending on the condition of the newborns in the early neonatal period, they were all divided into 4 groups. The 1st group included 790 children who had a good condition at birth, the 2nd group comprised 12 children with the initial signs of the impaired condition, the 3rd group included 10 newborns in a state of moderate severity, and the 4th group included 5 children whose condition was considered severe, or who died in the perinatal period. One child died due to vein thrombosis of the umbilical cord, the other - as a result of non-immune dropsy.

This investigation was carried out using the fully automated and computerized antenatal fetal monitor of the latest generation with a significantly improved computer program produced by Unicos, Moscow. In addition to the record of the heart rate, the main distinctive advantage of this device was recording and analyzing rapid and slow and hiccup-like movements of the fetus (Figure 1).

Rapid and hiccup-like movements as well as the fetal heart rate were recorded by the same Doppler sensor. A special computer program was developed to differentiate rapid and hiccup movements. To distinguish them, rapid movements were displayed in red, and hiccup movements were displayed in green on the monitor screen. The hiccup movements distinguished from rapid movements, because the first ones were recorded by separate groups, while the latter were isolated and chaotic in nature. Rapid and hiccup movements were counted automatically, and their numerical values were displayed on the monitor screen.

Slow movements were recorded by a tailored toco sensor, which is usually used for recording uterine contractions, and the sensitivity of which was increased by means of special computer processing. When assessing slow movements, the rate of their intensity and expression in conventional units (CU) was calculated.

To this end, we initially established that applying a weight of 50 g to the sensor leads to a shift in the indicator line of the instrument by 1 vertical scale division and is equal to 28.4 g /cm2, which we took as 10 CU. The action of 100 g weight led to a deviation of the indicator line by 2 vertical divisions, which was equal to 56.8 g / cm2. Therefore, these data indicate that there is a directly proportional linear relationship between these quantities, which allowed us to quantify their intensity on the basis of calculation of the intensity rate of slow movements by its duration. We calculated this rate as the sum of products of the amplitudes of slow movements by their duration and expressed in CU.

To obtain visual information, this device is equipped with a display that shows the fetal heart rate and the basal rhythm level; it also records accelerations, decelerations, rapid, slow and hiccup movements of the fetus, and shows all the necessary calculated values. The fetal status is evaluated using the FSI (fetal status indicator) value. Depending on its condition, the FSI value varies from 0 to 4. The FSI values from 0 to 1 indicate a normal fetal status, 1.1-2 indicate initial signs of the impairment of its condition, the values of 2.1 to 3 indicate its expressed intrauterine suffering, and values from 3.1 to 4 indicate a pronounced or critical impairment of its condition. In addition, the monitor screen displays the patient's full name and age, as well as the gestation age, date and time of the assessment. All information is stored in the archive of the monitor, and printed in any number of copies on ordinary writing paper using a conventional printer. One of the most important operating features of this device is the assessment completion message displaying on the monitor screen.

Results

Our investigation showed that among the fetuses we surveyed (n=818) the diagnosed impairment or non-impairment of their status was correct in 812 cases (99.3%). The normal status was found in 783 (99.4%) of 792 fetuses (FSI <1). The impairment of the status (FSI >1) was revealedin 25 (sensitivity was 96.2%) of 26 fetuses that were born with signs of intrauterine hypoxia or died in the perinatal period. An erroneous diagnosis was made only in one fetus, which died during pregnancy as a result of the umbilical cord vein thrombosis.

It should be noted that the important distinctive features of this monitor, contributing to an increase in the accuracy of the fetal status assessment are possible correction for sleep, a differentiated record of fetal motor activity (rapid, slow and hiccup movements), and if necessary the automatic prolongation of the survey.

Correction for sleep in our observation occurred in 96 cases (11.8%). Before correcting for sleep, the FSI value

Figure. CTG performed using the automated antenatal fetal monitor produced by *Unicos*
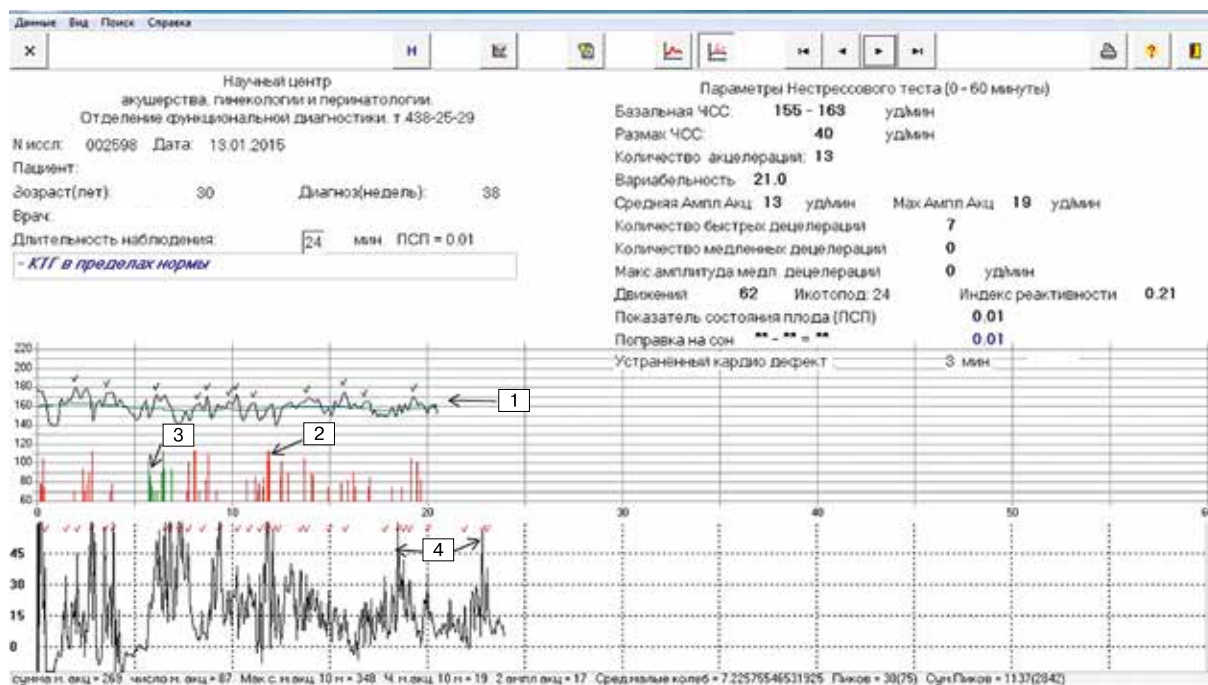
1 – fetal heart rate;
2 – rapid movements (chaotically positioned bursts);
3 – hiccup-like movements (compactly positioned bursts);
4 – slow movements (high bursts with a sharp apex).

ranged from 0.40 to 2.2. After the correction it decreased on average by 0.72 and was 0.21 and 1.4, respectively.

The motor activity during the survey was considered in 101 (12.3%) observations. Before the fetal movements were recorded, the FSI value varied from 0.9 to 2.81. After it was recorded, it decreased on average by 0.82 and was 0.56-1.07.

The survey of 60 (7.4%) fetuses provided indications of prolonging the investigation. The FSI value for 60 minutes of observation ranged from 1.12 to 39.1. After the investigation was prolonged, it decreased onaverage by 0.91 and was 0.23 and 3.52, respectively.

Data presented here show that during the automated antenatal fetal CTG, the frequency of corrections was generally found in almost every third (31.3%) observation, and the FSI value decreased by 0.82. This resulted in increase in the accuracy of a correct assessment of presence or absence of fetal impairment on average by 14.5%, which approached the maximum possible value and was 99.4%.

The main advantages are also the possibility of recording and analyzing the monitor curves at 22-25 weeks gestation, which is important in the early retardation of fetal development, and a short survey period of 27 minutes on average.

Discussion

It should be noted that at present CTG is the leading method of assessing the fetus status, which is included in the list of mandatory assessments of all pregnant women in developed countries. At the same time,

when applying this method of investigation, it should be kept in mind that the informational value of devices intended for these purposes is different. As numerous clinical observations show that the devices, where the assessment of the fetal status is based on the visual assessment of CTG have the lowest diagnostic accuracy. Thus, according to the data summarized by M.V. Medvedev et al. [16], the discrepancy in interpreting the same monitor curves even by experienced American specialists varies between 37-78%. Moreover, it was also found that the difference in the interpretation of the same curves by the same expert made after a while reached 28%. The low informational value of the visual assessment of CTG is also evidenced by careful studies conducted by I.K. Sigizbaeva [18].

According to the results of her studies, the accuracy of this method of CTG assessment was 68-70%. K.A. Keegan and R.H. Paul [19], having compared the CTG data, the gas composition of blood and evaluation of the conditionof a newborn using the Apgar score, concluded that the accuracy of thecorrect evaluation of the fetal status with a normal monitor curve ranged from 94 to 99%, whereas with a pathological curve it was only 50%. Approximately the same data with the most detailed analysis of all elements of the monitor curve were also obtained by E.N. Zelenko [20]. According to his data the sensitivity of the visual assessment of the monitor curve was 98% and the specificity was 54%.

In the late 70s - early 80s in order to improve the accuracy of visual assessment of CTG, the methods of its scoring were developed. W.M. Fischer et al. [21], H.B. Krebs, R.T. Petries [22], E.S. Gautier et

al. [23] were their authors. However, the detailed analysis of the diagnostic value of this method of CTG calculation performed by I.K. Sigizbaeva [18] showed its poor informational value. The accuracy of a correct evaluation of the fetal status with its use was 73-76%.

It is noteworthy that some manufacturers while using the scoring method of CTG evaluation with the automatic calculation of some parameters that are well defined with visual assessment of the monitor curve present their devices as computerized. Thus firstly, they mislead the consumer, and secondly, discredit the really computerized technique. Since the latter should include only the devices which can be used for obtaining the necessary information with appropriate computer equipment and specially made programs.

In this regard the investigations undertaken by J. Bernandes et al. [24] were of particular interest. The authors using the adapted FIGO criteria for computer analysis concluded that when dividing the monitor curves into 3 groups (normal, suspected pathology and pathology) the sensitivity and specificity of this technique turned out to be relatively low and was 83% and 80%, respectively (81.5% on average).

It should be noted that currently there are only two devices used in pregnancy and meeting the two above requirements. These are Soncaid (UK) and Unicos (Russia). However, our comparative analysis of the informational value of these two devices had shown considerable advantages of the latter.

The first of them uses a computer program developed by G. Dawes et al. [25] which calculates the STV value based on the mathematical analysis of the variability of heart rate pulse intervals, as well as the determination of some other elements of CTG. However, the accuracy of the assessment of fetal status only with the calculation of these parameters was poor and according to data of E.V. Pavlovskaya [26] was only 67%. But inclusion of fetal movements in this program as was previously proposed by H.B. Krebs et al. [22], made it possible to increase the accuracy of the assessment of its condition to 80% on average.

It is noteworthy that there are different points of view regarding the informational value of the automated Sonicaid system. For example, S.V. Shamarin [27] points out the very high accuracy of a correct assessment of fetal status when using these devices, which is 92.1%. At the same time N.G. Pavlova [28] who is very experienced in working with these devices, believes that in order to avoid mistakes, it is critical to rely on the experience of the doctor, although highly qualified specialists working in this field in her opinion are few.

From our point of view in the evaluation of the informational value of the Sonicaid system devices particular attention should be given to investigations based on the determination of the pH of the fetal blood. Thus A.M. Ventzileos and E.R. Guzman [29] having analyzed the survey of 38 fetuses with the retarded intrauterine development found that the sensitivity of various indices of this system with respect to pH <7.20 varied from 87.5 to 100%, the specificity was 73.3% and the average accuracy was 82.4%. G. Rizzo et al. [30] having surveyed 45 fetuses with the retarded intrauterine development born via Cesarean section found that

computerized CTG analysis allowed to identify acidemia antenatally (pH <7.21) with a sensitivity of 61.9% and a specificity of 91.6% (mean accuracy of 72.8%).

E.R Guzman and A.M. Vintzileos [31] demonstrated that the use of automated CTG makes it possible to exclude acidemia in 80% of cases, establish pre-acidemia in 100% of cases and acidemia in 62% of cases. The average accuracy of the differentiated assessment of the fetal status is 80.7%. L. Chung et al. [32] as the threshold pH value <7.15 in 73 cases showed that the sensitivity, specificity and the average accuracy of the obtained results were 87.5%, 75% and 81.2%, respectively.

The main distinguishing feature of Unicos unlike many manufacturers was the constant improvement of the equipment it produced. This in particular resulted in the accuracy of a correct assessment of the fetal status increasing from 84.4% in 1994 [33] to 91.2% in 2001 [34] due its use.

The great practical importance of the antenatal monitor developed by Unicos is confirmed by clinical observations. In particular our analysis of perinatal mortality in 23 maternity hospitals in the country where the observation period ranged from 2 to 7 years showed that perinatal mortality in them decreased on average by 33% [1]. Approximately the same data on the reduction of perinatal mortality were obtained in one of the administrative districts of Moscow with population was one million fifty thousand people. A comparative analysis of perinatal mortality for the period from 2003 to 2007 when the antenatal monitor was used compared to the same period when it was not used showed its reduction on average by 40% and variation from 4.5-4.8% [35]. The analysis of perinatal mortality in the last 16 years in the First Policlinic of the President's Medical Center allowed to establish that perinatal mortality for this period of observation averaged 1.5% [36] in this healthcare facility.

Our studies showed that the accuracy of a correct assessment of the fetal status with the use of the antenatal fetal monitor of the last generation by Unicos was on average 99.4%.

It is noteworthy that such high accuracy of the obtained results was achieved due to the simultaneous registration and comparison of several parameters under investigation and the automatic selection of the most optimal of them. It should be added that sufficiently reliable information on the fetal status using this device may be obtained from the 22nd - 25th weeks; the minimum duration of the survey in individual cases is 2 minutes.

However, considering certain skepticism in the accuracy of the results obtained with such a short recording of the monitor curves on the part of both patients and doctors we increased its minimum duration to 10 minutes in such cases.

It is noteworthy that according to the current opinion at this stage of medical equipment development automated CTG does not always allow to obtain an adequate result, and an experienced doctor who is well familiar with this technique can do what a computer cannot do [28]. But our investigations do not allow us to share this point of view. Thus, in more than 20 cases where the doctor disagreed with the results of the automated analysis,

further observation of the condition of the newborn showed that his opinion was erroneous in all cases.

Therefore, we consider that the following advantages of the monitor we use are the most significant in comparison with other similar devices:

A higher accuracy of fetal status evaluation that approaches 100%.

The possibility of a differentiated evaluation of the fetal status based not on 2 (normal, pathology), but on 4 groups (normal, impaired condition, condition of moderate severity, severe condition).

Very highly differentiated accuracy of fetal status evaluation comprising 87% that cannot be obtained using other similar devices.

The possibility of evaluation of the fetal status not from the 34th week as in the conventional CTG analysis but at 22-25 weeks gestation.

Low cost of the device.

Fully automated processing of the obtained information.

Unification of results and absence of subjectivity in the analysis of CTG.

Automatic estimation of the length of a survey. The minimum time of an examination is 2 minutes; that of clinical practice is 10 minutes.

Almost complete elimination of the effect of the fetal sleep on the final result.

Registration and recording of various manifestations of motor fetal activity (rapid, slow and hiccup-like movements).

Establishing the fact of recording of the heart rate from the aorta of a woman without direct recording of her cardiac activity.

Automatic elimination of short-term and long-term artifacts in the event of a temporary cardiac signal loss.

The possibility of assessing the fetal status with a complete loss of cardiac signal based on the assessment of its motor activity.

Unlimited storage of a large amount of information and its reproduction at any time.

The possibility of CTG recording of two women simultaneously with a single device.

Reproduction of data obtained and monitor curves on ordinary writing paper, which significantly reduces the cost of the survey.

Reduced time spent on the survey.

Use at any obstetrical institution, as well as home, without direct involvement of medical personnel.

Accelerated training of specialists for CTG interpretation.

High quality of monitor curves almost excludes erroneous results with the automated reading of CTG.

Conclusion

In conclusion it should be noted that antenatal CTG using the device produced by Unicos is a highly informative method, the use of which allows to assess the functional fetal status in the second half of pregnancy with sufficient accuracy. This is especially important in healthcare facilities with a lack of specialists who are able to perform a quality evaluation of CTG. It should also be considered most appropriate to use them in obstetrical institutions with high perinatal mortality and in regions where it significantly exceeds the average data in Russia.

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