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Diagnosis and treatment of infection specific to the perinatal period (Draft clinical recommendations for discussion by neonatologists and pediatricians)

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ABSTRACT

Perinatal infections occupy a leading place among the causes of neonatal morbidity, maternal and perinatal mortality. Infections are among the main causes of termination of pregnancy and premature birth. The practical recommendations presented in the work are intended for doctors of obstetric institutions in order to make a clinical diagnosis of an infection specific to the perinatal period, the tactics of examination and treatment of newborn children. The clinical recommendations correspond to the latest scientific data on the topic, contain information that is applied to the practical activities of a neonatologist, intensive care specialist and pediatrician. These clinical recommendations contain information about infections specific to the perinatal period, including the definition, frequency of occurrence, etiology of infections, pathogenetic mechanisms of disease development Numerous high-risk factors for infection of the fetus and newborn are described in detail. The document discusses and proposes the classification of the disease, the criteria for the adoption of the diagnosis. The features of the clinical picture of the disease are described, it is noted that the inflammatory process in a newborn child can be localized in any organ or acquire a systemic (generalized) character, in some cases, the ingress of an infectious agent into a macroorganism is not necessarily accompanied by clinical manifestations, which indicates an asymptomatic or subclinical course of infection. The recommendations provide advanced laboratory and instrumental diagnostics. The stages of treatment are described, including the choice and correction of antibacterial therapy, taking into account the peculiarities of the mother's anamnesis, the child's gestation period and the etiology of the disease. These clinical recommendations have been prepared taking into account the level of credibility of the recommendations and the level of reliability of the evidence.These practical recommendations are offered for public discussion and are posted in full on the website of the Ministry of Health of the Russian Federation.

Keywords: newborns; infection specific to the perinatal period; diagnosis; treatment; practical guidelines; clinical guidelines.

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Диагностика и лечение инфекции, специфичной для перинатального периода (Проект клинических рекомендаций для обсуждения неонатологами и педиатрами)

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АННОТАЦИЯ

Перинатальные инфекции занимают ведущее место среди причин неонатальной заболеваемости, материнской и перинатальной смертности. Инфекции относятся к основным причинам прерывания беременности и преждевременных родов. Практические рекомендации, представленные в работе, предназначены для врачей родовспомогательных учреждений с целью постановки клинического диагноза инфекции, специфичной для перинатального периода, тактики обследования и лечения новорожденных детей. Клинические рекомендации соответствуют последним научным данным по теме, содержат информацию, которая носит прикладной характер для практической деятельности врача неонатолога, реаниматолога и педиатра. В данных клинических рекомендациях содержится информационная справка об инфекциях, специфических для перинатального периода, включающая в себя определение, частоту встречаемости, этиологию инфекций, патогенетические механизмы развития заболевания. Подробно описаны многочисленные факторы высокого риска инфицирования плода и новорожденного. В документе обсуждается и предлагается классификация заболевания, критерии установления диагноза. Описаны особенности клинической картины болезни, отмечено, что воспалительный процесс у новорожденного ребенка может локализоваться в каком-либо органе или приобретать системный (генерализованный) характер, в ряде случаев попадание инфекционного агента в макроорганизм не обязательно сопровождается клиническими проявлениями, что свидетельствует о бессимптомном или субклиническом течении инфекции. В рекомендациях представлена расширенная лабораторная и инструментальная диагностика. Расписаны этапы лечения, включая выбор и коррекцию антибактериальной терапии, с учетом особенностей анамнеза матери, срока гестации ребенка и этиологии заболевания. Данные практические рекомендации подготовлены с учетом уровня убедительности рекомендаций и уровня достоверности доказательств, предлагаются к обсуждению общественности и в полном виде представлены на сайте Минздрава России.

Ключевые слова: новорожденные; инфекция, специфичная для перинатального периода; диагностика; лечение; практические рекомендации; клинические рекомендации.

Как цитировать

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INTRODUCTION

Infections specific to the perinatal period are one of the most burning issues in modern perinatology, as they are the main cause of morbidity, as well as of maternal and perinatal mortality. Within the context of modern realities, a physician at an obstetric facility needs clear algorithms of actions for an accurate diagnosis, as well as patient treatment strategy that comply with the principles of evidence-based medicine. The recommendations below were compiled exactly to address this issue.

DEFINITION

Infections specific to the perinatal period (IPPs) are infectious processes (inflammations) occurring in various organs and/or systems of the fetus during the period from the 22nd full week (154th day) or the newborn up to the 7th day of extrauterine life (168 hours). These infections are characterized by clinical and pathomorphological changes typical for infectious diseases, which can be detected either antenatally or after birth [5, 16, 17, 30].

According to the International Statistical Classification of Diseases and Related Health Problems, 10th revision, IPPs are coded as P39.8 Other specified infections specific to the perinatal period; P39.9 Infection specific to the perinatal period, unspecified; P37.9 Congenital infectious or parasitic disease, unspecified.

When a perinatal, congenital, or parasitic infection is identified by etiology, the corresponding nosological codes are used: P23, P37.0–37.5, and P39.0–39.4.

EPIDEMIOLOGY

From 2017 to 2020, the incidence of perinatal infections (IPPs) in newborns in the Russian Federation was approximately 1.4% [18]. In obstetric hospitals, the infectious morbidity rate for premature infants weighing 1000 g or more was 8%, while for infants with extremely low birth weight (ELBW), it was around 27%. The mortality rates were 1.6% and 21%, respectively. Infections specific to the perinatal period are reported in 2.3% of live-born children and account for 6% of early neonatal morbidity [33]. IPPs are to be recorded and registered in the infectious disease register at the location of detection, within medical institutions and territorial bodies responsible for federal state sanitary and epidemiological supervision.

DISEASE ETIOLOGY AND PATHOGENESIS

Perinatal infection is the leading cause of morbidity, maternal and perinatal mortality. Infection is the main cause of pregnancy termination and premature birth. The term “perinatal infections” is usually applied to infections transmitted from a mother to a child during intrauterine development (intrauterine/congenital), during childbirth (perinatal, or intranatal), immediately after childbirth (postnatal) with their development in the early neonatal period of life.

The causative agents of perinatal infections are diverse [5, 18, 24, 33, 74, 81–83, 119, 122]. These may be bacteria (Group *B streptococcus, Escherichia coli, Enterobacter aerogenes, Klebsiella* spp., *Pseudomonas aeruginosa, Staphylococcus epidermidis, Staphylococcus aureus, Haemophilus influenza, Klebsiella pneumoniae, Streptococcus pneumoniae, Treponema pallidum, Listeria monocytogenes, Mycobacterium tuberculosis*), viruses (*Herpes simplex virus, Cytomegalovirus, Respiratory syncytial virus, Rubella*, etc.), atypical pathogens (*Chlamydia trachomatis, Ureaplasma urealyticum, Mycoplasma hominis, Mycoplasma pneumonia*, etc.), fungi (*Candida* spp.), protozoa (*Toxoplasma gondii*).

The fundamental difference of IPP is its proven relation of the infection to the mother’s body. In a normal pregnancy, the fetus is well protected by the placenta and amniotic membranes from any various pathogenic and opportunistic microorganisms. A pathological course of pregnancy, caused primarily by infectious causes, facilitates the penetration of pathogens into the fetus, crossing the placental barriers (transplacentally or ascendingly), contributing to the development of an inflammatory reaction in the fetus in microbial invasion.

In the vast majority of cases, fetal infection begins with damage to the placenta. The infectious and inflammatory process in the placenta and in the amniotic membranes — intra-amniotic infection — adversely affects vital functions of the fetus. Through the bloodstream, pathogenic microorganisms enter the chorionic villi of the placenta, where they become fixed and form an inflammation focus.

The negative effect of antenatal infection on the feto-placental complex depends on several factors, including the gestational age at the time of infection, the type of pathogen, its virulence, the extent of seeding, whether the infection is primary or secondary in the pregnant woman, the route of infection to the fetus, the degree of prevalence, the intensity of the inflammatory process, and the severity and nature of changes in the immune response of a pregnant woman.

Antenatal infectious agent achieves the fetus hematogenously (transplacentally) or through infected amniotic fluid by an ascending (from the cervical canal) or descending (from the fallopian tubes) route, by transmembranal route (through the amniotic membranes in endometritis, placentitis), iatrogenically (during medical manipulations), or by contact [13, 32, 33]. Most microorganisms, having entered the uterine cavity, stimulate the infiltration and activation of neutrophils and lead to

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an increase in the synthesis and release of proinflammatory cytokines, prostaglandins and matrix metalloproteases. These changes contribute to cervical maturation, membrane rupture, uterine contractions, and premature amniotic fluid discharge [4, 5, 33, 41].

Perinatal infection and the development of a systemic inflammatory process in a fetus with activation of its immune system often leads to premature birth and proven intra-amniotic infection [76, 77, 95, 114]. Newborns from mothers with chorioamnionitis are at high risk in terms of development of neonatal sepsis, bronchopulmonary dysplasia, intraventricular hemorrhage, periventricular leukomalacia, and neonatal death.

High-risk factors of fetal infection are inflammatory diseases of the uterus and its appendages, colpitis, bacterial vaginosis, oligohydramnios or polyhydramnios, complicated obstetric and gynecological history (repeated artificial termination of pregnancy with complicated postabortal period, habitual miscarriage, congenital malformations and antenatal death of a fetus), placental insufficiency, intrauterine growth and fetal development retardation, use of immunosuppressive therapy, surgical correction of isthmic-cervical insufficiency, immunodeficiency conditions [25, 30, 96].

The development of the infectious process can manifest in congenital malformations (CM), premature delivery, growth and development retardation, intrauterine death, and clinical signs of infection immediately after birth and/or after several hours or days (if the infection occurred intranatally).

The inflammatory process can be localized in any organ or become systemic (generalized); in some situations, the penetration of an infectious agent into a macroorganism is not necessarily accompanied by clinical manifestations, which indicates an asymptomatic or subclinical course of infection [4, 6, 15–18, 30, 117, 118]. Transformation of an infection into a generalized process is determined by factors that reduce the body reactivity, namely the development of intrauterine and intranatal hypoxia, primary and secondary immunodeficiencies [27–29].

To prevent intrauterine infection, all triggering factors are taken into account. Their possible impact shall be excluded starting from the pregravid stage and throughout pregnancy and until childbirth.

CLASSIFICATION

There is no approved general classification of IPP. The ICD code X P39.8 should be used to encode infections if a newborn in the first week of life shows clinical and laboratory signs of an inflammatory reaction with the identification of a specified pathogen [viral, bacterial, parasitic, fungal, mixed (polymicrobial, viral-bacterial)] and/or with the presence of an infectious focus, the case of which is not specified in the clinical recommendations and ICD X.

Code P37.9, P39.9 Infection, unspecified should be used to encode a case when a newborn in the first week of life shows clinical, laboratory and/or morphological signs of an inflammatory reaction without identification of the pathogen and localization of the inflammatory focus.

CLINICAL PATTERN

Early clinical symptoms of congenital/perinatal infections usually do not have specific manifestations. Immediately after birth, certain conditions may be detected in a newborn that indicate an unfavorable course of the intrauterine period (signs of intrauterine growth retardation), morphofunctional immaturity, congenital malformations, multiple dysmorphias, birth in a state of asphyxia against the background of chronic intrauterine hypoxia). From the first hours or in the first days of life (72 h), signs of deterioration in the condition increase as manifestations of infectious toxicosis: impaired thermal regulation [unstable temperature (≥38.5°C or ≤36.0°C), inability to retain heat independently], “marbling,” pale skin with a grayish shade, perioral cyanosis and/or acrocyanosis, sclerema, jaundice of unknown origin, early and prolonged yellowness of the mucous membranes and skin, polymorphic hemorrhagic rash (isolated, punctate petechiae, ecchymosis, confluent erythema, large hemorrhagic and necrotic foci, from birth or in the early stages, of different localization), other manifestations of hemorrhagic syndrome (gastric, pulmonary hemorrhage, macrohematuria, bleeding from skin puncture sites). A newborn may have a decreased or absent sucking reflex, refusal to eat, lethargy, muscle hypotonia, hyperesthesia, excitability or depression. Episodes of hypoglycemia or hyperglycemia, edema syndrome, respiratory disorders (apnea and/or tachypnea, increased need for oxygen, respiratory support), manifestations of cardiovascular failure [bradycardia (average heart rate (HR) less than 110 per minute) and/or tachycardia (average HR over 180 per minute)], other rhythm disturbances, arterial hypotension (mean arterial pressure less than the 5th percentile for the gestational age) are reported. Dysfunction of the gastrointestinal tract is possible (intolerance to enteral nutrition, abdominal distension, weakened or absent peristalsis during auscultation).

In the presence of a perinatal-specific manifest/severe infection, the following symptoms and syndromes may be present: sepsis-like syndrome (differential diagnosis is carried out with early neonatal sepsis), hepatosplenomegaly, cytopenia (usually monoleukopenia, thrombocytopenia), pneumonitis, hydrothorax, hepatitis, often cholestatic, pathological jaundice, enterocolitis/hemocolitis, and ascites.

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Clinical manifestations of infection in intrauterine (antenatal) or intranatal infection in a newborn child most often occur in the first 72 hours of the child's life (early infections); in the group of children born with an extremely low body weight, manifestation may be delayed up to 5–7 days of life. In 85% of cases, symptoms of an infectious disease appear in the first 24 hours of life, often 6–8 hours after birth (very early infections), in 5% within 24–48 hours, in 10% signs of infection appear on the 2–3rd day of life. In premature babies, the first clinical signs appear from the moment of birth with the manifestation of respiratory disorders, which masks them as respiratory distress syndrome (RDS) of the newborn.

General clinical signs in the diagnosis of infectious and inflammatory process in newborns caused by perinatal infection have non-specific symptoms. It is important to conduct differential diagnosis with other infectious nosological entities, including, first of all, early neonatal sepsis and congenital pneumonia.

To confirm the diagnosis of PIS, the requirements are:
- thorough collection of the mother's perinatal history;
- physical examination of a newborn with identified one or more symptoms of the disease (see the Clinical Pattern section);
- laboratory and instrumental studies to exclude the source of infection [lungs, urinary system, gastrointestinal tract (GI), central nervous system (CNS)].

It is recommended to study the mother's medical history to identify the risk group for IPP development [5, 11, 30, 39, 46, 49, 52, 57, 58, 62–65, 68, 75–77, 97, 99, 109, 110, 119, 120]: the grade of recommendations is C (the level of evidence is 3).

Comments. Maternal risk factors for the development of IPP include:
- the presence of an acute infectious and inflammatory disease or exacerbation of a chronic infectious and inflammatory disease;
- invasive obstetric diagnostic or therapeutic procedures;
- the presence of clinical signs of acute and persistent, including bacterial, infections before or during childbirth;
- prolonged and frequent hospitalization of a mother during this pregnancy, multiple courses of antibacterial, hormonal and/or cytotoxic therapy;
- laboratory data pf a mother before delivery: elevated C-reactive protein (CRP) level, leukocytosis (excluding leukocytosis after recent administration of corticosteroids);
- detection of pathogenic microorganisms in the mother's birth canal, primarily group B streptococcus or its antigens;
- pre-delivery discharge of amniotic fluid (anhydrous interval ⩾18 hours);
- increase in maternal body temperature during delivery ⩾ 38 °C for more than 2 h;
- intrauterine interventions during pregnancy;
- antibiotic therapy of a mother immediately before delivery or during delivery with protected penicillins or reserve antibacterial drugs;
- clinical manifestations of chorioamnionitis or other intra-amniotic infection;
- consumption of raw meat, raw eggs, raw milk, or contaminated vegetables and fruits, or contact with cat feces during pregnancy (*Toxoplasma gondii*) by a mother;
- vaginal delivery in the presence of primary maternal infection induced by herpes simplex virus types 1 or 2 (*Herpes simplex virus types 1, 2*);
- seronegative mothers who develop primary infection during pregnancy (cytomegalovirus) or exacerbation of cytomegalovirus infection in seropositive pregnant women (see Clinical Guidelines on Congenital Cytomegalovirus Infection [1]);
- human immunodeficiency virus infection in a mother;
- consumption of dairy products and food without proper thermal treatment *(Listeria monocytogenes*);
- bacteriuria during pregnancy.

The main symptoms of chorioamnionitis in any combination include febrile fever (body temperature 38.0°C), maternal tachycardia (100 beats/min), fetal tachycardia (160 beats/min), purulent or purulent-bloody vaginal discharge, sometimes with a foul odor [65, 67]. In terms of diagnosis, histological examination of the placenta is of great importance with the detection of typical inflammatory changes in the vessels of the fetal part of the placenta and the wall of the umbilical cord (deciduitis, funisitis, vasculitis, placental tissue infiltration), which suggests the possible development of an infectious process in a newborn and serves as an additional criterion in verifying the diagnosis of a viral infection or IPP (placental examination is mandatory to confirm the diagnosis) [9, 28, 29, 43, 51, 56]. Signs of chorioamnionitis: the presence of inflammation of the fetal membranes, amniotic fluid and decidual tissue.

Additional risk factors for the development of IPP include: preeclampsia and other pregnancy complications in a mother; vitamin D deficiency; premature rupture of membranes; meconium-stained amniotic fluid with a specific odor; premature birth; fetal distress; perinatal hypoxia and asphyxia during childbirth; death of children in the family from severe bacterial infections at the age of up to 3 months (suspected primary immunodeficiency).

When collecting the mother's medical history, it is important to confirm the infection by microbiological (cultural) examination of the discharge from the female genital organs (and/or amniotic fluid) for aerobic and

[1] https://cr.minzdrav.gov.ru/recomend/260_2

facultative anaerobic microorganisms, and to conduct reasonable antibiotic therapy in order to reduce neonatal morbidity and purulent-septic complications in the mother.

It is also necessary to study mother's vaccination information, epidemiological history, occupational hazards (work in children's groups, work with animals, etc.), traveling, especially during pregnancy (typical for infections caused by the Epstein–Barr virus, malaria, dengue fever, Zika virus, etc.), the presence of diseases with exanthema during pregnancy; features of the current pregnancy: thrombocytopenia of unspecified etiology, threat and premature birth, congenital malformations, fetal growth retardation, fetal hydrops, previous missed miscarriages and antenatal death, placental insufficiency, polyhydramnios and oligohydramnios.

Neonatal factors include prematurity and intrauterine growth retardation, especially of the dysplastic type, multiple dysmorphias, congenital malformations and structural anomalies.

LABORATORY AND INSTRUMENTAL DIAGNOSTIC STUDIES

For a newborn with a suspected IPP, it is recommended to conduct a general (clinical) blood test, detailed with leukocyte and platelet counts, neutrophil index (NI), absolute neutrophil count, to detect any inflammatory changes with a repeat test at the age of 48–72 hours and at the end of the antibiotic therapy to decide on its cancellation or continuation (change) [11, 12, 14, 71, 82, 87, 94, 98, 101, 106, 115]: the grade of recommendations is B (the level of evidence is 3).

Comments. An elevated NI level and a low absolute neutrophil count are predictors of infection in newborns. The sensitivity of the absolute neutrophil count is 78%, the specificity is 73%, the sensitivity of NI is 78%, the specificity is 75%.

For a newborn with a suspected IPP, it is recommended to conduct a microbiological (culture) test of blood for sterility from the umbilical cord or peripheral vein and determine the sensitivity of microorganisms to antimicrobial chemotherapeutic drugs in order to detect and identify the pathogen, exclude sepsis in a newborn and determine the strategy of the antibiotic therapy [21, 23, 42, 45, 66, 82, 89, 91, 101, 106, 116, 120, 128]: the grade of recommendations is B; the level of evidence is 3.

Comments. A quick culture method (QCM, Shell vial assay) is preferred, if a medical institution (HF) has the possibilities. Umbilical blood culture has high sensitivity and specificity for diagnosing intrauterine infection of bacterial etiology. Modern microbiological studies can distinguish true bacteremia from contamination in blood culture (given the MI's possibilities). Blood culture is considered negative for gram-negative microorganisms if there is no growth within 48 hours, and for gram-positive microorganisms if there is no colony growth within 72 hours. Upon that, blood culture is highly likely to be contaminated if colony growth occurs after 72 hours of incubation. Modern systems can identify a pathogen in 77, 89, 94% of cases 24, 36 and 48 hours after blood sampling, respectively. The absence of a positive result of blood culture of a pathogen DOES NOT exclude the presence of an infectious process in a newborn (given the MI's possibilities)

In case of tracheal intubation for a newborn with a suspected course of IPP, it is recommended to conduct a microbiological (cultural) study of sputum for aerobic and facultative-anaerobic microorganisms, sputum for fungi (yeast and mycelial) and determine the sensitivity of microorganisms to antimicrobial chemotherapeutic drugs to identify the pathogen, exclude pneumonia and determine the strategy of antimicrobial therapy [22, 44, 59, 91, 101, 106, 116, 120, 128]: the grade of recommendations is A (the level of evidence is 3).

Comments. A quick culture method (QCM, Shell vial assay) is preferred, given the MI's possibilities.

In the presence of risk factors for the development of IPP or clinical and/or laboratory signs of infection in a mother, for a newborn with a suspected IPP it is recommended to perform selective identification of DNA of *Epstein–Barr virus*, *Cytomegalovirus*, *Parvovirus B19*, herpes virus type 6 (*HHV6*), toxoplasma (*Toxoplasma gondii*), RNA of *Rubella virus* by polymerase chain reaction (PCR) in peripheral and umbilical cord blood, quantitative examination, determine DNA of *Treponema pallidum*, chlamydia (*Chlamydia* spp.), streptococci (*Streptococcus agalactiae*, *SGB*, *Streptococcus pyogenes, SGA*), *Haemophilus influenzae*, *Varicella-Zoster virus*and lichen in blood by PCR, quantitative study of herpes simplex types 1 and 2 (*Herpes simplex virus types 1, 2*), listeria (*Listeria monocytogenes*), *Pseudomonas aeruginosa*, by PCR in blood, quantitative examination, molecular biological study of urine for ureaplasma (*Ureaplasma* spp.) with species specification, molecular biological study of upper respiratory tract secretions for *Mycoplasma hominis*, molecular biological study of bronchoalveolar lavage fluid, sputum, endotracheal aspirate [if a child is on artificial ventilation (ALM)] for methicillin-sensitive and methicillin-resistant *Staphylococcus aureus*, methicillin-resistant coagulase-negative *Staphylococcus* spp., molecular biological examination of sputum, bronchoalveolar lavage fluid (if a child is on mechanical ventilation) for *Cytomegalovirus* to identify pathogens of IPP [4, 10, 18, 19, 20, 33, 66, 101]: the grade of recommendations is B (the level of evidence is 2).

Comments. Conducting a blood test by the PCR method depends on the technical capabilities of the MI's

laboratory. If there is no possibility to conduct a quantitative study, a qualitative study is acceptable. Upon receipt of the results of molecular genetic tests confirming the origin of the infectious process, further strategy of managing a child is implemented in accordance with the existing clinical guidelines for specific nosologies.

For a newborn with a suspected course of IPP, it is recommended to conduct study of the CRP level in blood serum with a control after 48–72 hours to identify signs of systemic inflammatory response syndrome (SIRS) and at the end of the course of antimicrobial therapy to determine the strategy of ABT (cancellation or continuation of therapy) [47, 48, 60, 67, 70, 86, 92, 103, 111, 134]: the grade of recommendations is B (the level of evidence is 2).

Comments. Reference values are determined by the method and type of analyzer used in the MI. CRP production starts 4–6 hours after development of the infectious process, it doubles after 8 hours and reaches the maximum peak after 36–48 hours. The assessment of CRP in the first 6–8 hours after birth has low sensitivity of 35–50% and false positive results in 30% [69, 70, 107, 112, 134]. In this regard, the study of the CRP level should be carried out 24–48 hours after birth (earlier if indicated), and monitoring shall be performed no earlier than 24–36 hours over time, which increases the sensitivity of this study to 74–98%, specificity to 71–94% [18, 47, 70, 92, 103, 112]. Non-infectious conditions of a newborn may influence the increase in the CRP level in the first 24–48 hours after birth: trauma, meconium aspiration syndrome, ischemic tissue damage and hemolysis [47, 60, 92, 103, 131]. An increase in the CRP level is an early sign of bacterial infection in full-term infants; in premature infants, such dependence has not been clearly proven (the sensitivity is 68.5%, the specificity is 85.5%) [47].

Determination and assessment of other SIRS markers to exclude a generalized infectious process (neonatal sepsis) is carried out according to indications (given the MI's possibilities):

- determination of the presepsin level in blood (sensitivity 80–94%, specificity 75–100%). It is known that the presepsin level does not depend on: gestational age, body weight, early postnatal age, method of delivery. Studies of the level of presepsin and interleukin6 (IL6) are not used to determine further strategy of antimicrobial therapy (cancellation, change, prolongation of the course), but only for early diagnosis of an infectious disease [3, 40, 79, 84, 85, 100, 104, 105];
- determination of IL6 levels in blood (sensitivity 83–95%, confidence interval 71–90%, specificity 87–95%, confidence interval 78–93%) [105, 124];
- determination of procalcitonin (PCT) levels in blood is assessed in accordance with the threshold value depending on the age (hours) after birth (sensitivity 87–94%, specificity 74–90%). In newborns, a physiological increase in PCT is observed during the first 48 hours of life, a sign of PCT infection of more than 2.5 ng/mL in the first 72 hours, after 72 hours — more than 2.0 ng/mL [50]. The PCT level increases in the first days after injury, surgery, severe burns, in patients with invasive fungal infections [79, 80].

Determination and correct assessment of inflammation markers, use of a combination of the above-specified markers in the diagnostic process increases the probability of identification of an infectious disease in a newborn [38, 40, 47, 48, 60, 67, 70, 79, 84, 85, 87, 92, 100, 103, 104, 105, 111, 124, 128, 127, 134].

For a newborn with a suspected IPP and the presence of neurological disorders typical for an infectious lesion of the central nervous system, it is recommended to perform a lumbar puncture and microscopic examination of the cerebrospinal fluid, cell counting in a counting chamber (determination of cytosis, protein level) to exclude meningitis/encephalitis [97]: the grade of recommendation is B (the level of evidence is 2).

Comments. Prior to performing a spinal puncture, it is necessary to stabilize the condition of a newborn (respiratory therapy, treatment of shock, seizures, hemorrhagic syndrome).

For a newborn with a suspected IPP and the presence of neurological disorders typical for an infectious lesion of the central nervous system, it is recommended to conduct a microbiological (cultural) study of the cerebrospinal fluid for aerobic and facultative-anaerobic opportunistic pathogens, determine DNA of the herpes simplex virus types 1 and 2 (*Herpes simplex virus types 1, 2*) in the cerebrospinal fluid by PCR [97]: the grade of recommendation is B (the level of evidence is 2).

Comments. Conducting a blood test of the cerebrospinal fluid by the PCR method depends on the technical capabilities of the MI's laboratory. If there is no possibility to conduct a quantitative study, a qualitative study is acceptable. Upon receipt of the results of molecular genetic tests confirming the origin of the infectious process, further strategy of managing a child is implemented in accordance with the existing clinical guidelines for specific nosologies.

For a newborn with a suspected IPP, a general (clinical) urine analysis is recommended to exclude urinary tract infection [97]: the grade of recommendation is B (the evidence level is 2).

For a newborn with a suspected IPP, it is recommended to conduct a microbiological (cultural) urine test for sterility [97] to exclude a urinary tract infection in the presence of pathological changes in the general (clinical) urine analysis: the grade of recommendations is B (the level of evidence is 2).

For a newborn with a suspected IPP and respiratory disorders, a chest X-ray is recommended to exclude pneumonia [18–22, 33, 34, 106]: the grade of recommendations is B (the level of evidence is 3).

Comments. It is necessary to determine the cause of respiratory disorders in a newborn and establish the appropriate diagnosis: congenital pneumonia, respiratory distress syndrome of the newborn, meconium aspiration syndrome, congenital malformations of the heart, congenital malformations of the lungs, interstitial lung diseases, etc.

For a newborn with a suspected IPP, is recommended to perform echocardiography (EchoCG), neurosonography (NSG), ultrasound examination (US) of the abdominal cavity, kidneys and adrenal glands to assess the function of organs and systems [18–21, 33, 34, 108]: the grade of recommendations is B (the level of evidence is 3).

Comments. In case of concomitant disorders of various organs and systems, EchoCG, NSG, ultrasound, ECG can facilitate timely prescription and correction of the symptomatic therapy. It is necessary to exclude various somatic diseases, primarily congenital malformations of the heart, lungs, intestines, kidneys.

For newborns with dysfunction of organs and systems, in order to control vital functions and differential diagnosis, it is recommended to conduct daily bedside monitoring of the heart rate, respiratory rate, blood pressure (including systolic), SpO_2, body temperature, diuresis rate [18–21, 33, 34, 55, 118, 133]: the grade of recommendations is B (the level of evidence is 3).

Comments. In case of concomitant disorders of the function of various organs and systems, the above studies can facilitate timely prescription and correction of the syndrome-based and symptomatic therapy.

In the early neonatal period, it is necessary to differentiate IPP from the following conditions and nosological entities with confirmed etiology: intrauterine infections (congenital cytomegalovirus infection, herpes simplex virus types 1, 2, 6, toxoplasmosis); neonatal sepsis; RDS of newborns; congenital pneumonia; meningitis; carditis; necrotizing enterocolitis; congenital malformations of the heart, lungs, intestines, kidneys; diaphragmatic hernia, hereditary metabolic diseases; congenital metabolic disorders; asphyxia; transient tachypnea of the newborn; neonatal meconium aspiration; persistent pulmonary hypertension of the newborn.

Treatment of children with IPP includes conservative therapy:

1. Etiotropic empirical ABT is prescribed to newborns with clinical and/or laboratory and instrumental signs of probable or proven IPP, but without specified etiology.
2. Justified intensive (syndrome-based) therapy is carried out for indications: correction of metabolic, hemostatic disorders, manifestations of organ dysfunction.
3. Symptomatic therapy.
4. Reasonable feeding (total parenteral nutrition, partial parenteral nutrition, breastfeeding, feeding with breast milk substitutes, including adapted formulas).

For newborns with clinical and anamnestic risk factors, 1–2 or more clinical symptoms and/or laboratory and instrumental signs of probable or proven congenital (perinatal) infection, but without specified etiology, it is recommended to prescribe empirical ABT at early stages [1, 2, 7, 8, 26, 31, 35–37, 46, 53, 61, 66, 72, 78, 80, 90, 93, 99, 102, 121, 126, 130, 132]: the grade of recommendations is A (the level of evidence is 1).

Comments. Antibacterial therapy (ABT) in case of suspected development of IPP is indicated at early stages after birth for the following categories of children: patients with very low birth weight (VLBW) and extremely low birth weight (ELBW); newborns requiring invasive ALV since birth due to the severity of condition; newborns with neonatal seizures. It is recommended to start ABT no later than 2 hours of life, for newborns with ELBW — in the delivery room. For newborns weighing more than 1500 g at birth, ABT is prescribed for indications based on the results of the initial clinical and laboratory examination. ABT started if development of a perinatal-specific infection is suspected in the first day of life is cancelled in the absence of clinical, laboratory and instrumental data confirming the infection within 48–72 hours of life (after determining the CRP level, for PCT indication). If a diagnosis of a perinatal-specific infection is confirmed, the empirical ABT regimen is continued until the results of the microbiological study and the evaluation of the results of the clinical, laboratory and instrumental examination are obtained, with a subsequent decision on the cancellation or further prescription of targeted ABT (in accordance with the sensitivity of the isolated microflora). When the levels of SIRS markers and the results of the clinical, laboratory and instrumental examination of the newborn are normalized, ABT is canceled.

Initial ABT regimens:

Regimen A: provides for ABT for newborns whose mothers have an uncomplicated medical history. It is recommended to prescribe empirical ABT using broad-spectrum penicillins (ATC code J01CA; ampicillin) [126, 129] in combination with other aminoglycosides (ATC code J01GB; gentamicin, amikacin, netilmicin) or monotherapy with a combination of penicillins,

including combinations with beta-lactamase inhibitors (ATC code J01CR; ampicillin + sulbactam). In case of renal dysfunction, it is reasonable to decide on the cancellation of other aminoglycosides (ATC code J01CA) on an individual basis, taking into account the available medical history data and results of laboratory and microbiological examination of a patient;

Regimen B: involves ABT in newborns whose mothers have a history of aggravating factors: chorioamnionitis, intrauterine interventions, prolonged anhydrous interval (more than 18 hours), elevated CRP, fever during labor lasting more than 2 hours, antibiotic therapy in a mother immediately before labor and during labor, culturing of group B streptococcus from the cervical canal. Regimen B can also be considered in cases where there are risk factors for infection on the part of a newborn (for example, VLBW, ELBW, artificial ventilation). In this case, it is reasonable to prescribe a combination of penicillins, including combinations with beta-lactamase inhibitors (ATC code J01CR; ampicillin + sulbactam) and other aminoglycosides (ATC code J01GB; gentamicin, amikacin, netilmicin);

Preference is given to parenteral administration of systemic antimicrobial drugs (ATC code J; intravenous administration of drugs). It is not recommended to prescribe drugs containing amoxicillin + clavulanic acid (ATC code J01CR) due to a possible adverse effect of clavulanic acid on the intestinal wall, especially in premature infants. It is unreasonable to include cephalosporins of the 1st (ATC code J01DB), 2nd (ATC code J01DC), 3rd (ATC code J01DD) and 4th (ATC code J01DE) generations in the initial antibacterial therapy regimen due to the lack of activity against *Listeria monocitogenes* and *Enterococcus* spp., as well as the risk of development of necrotizing enterocolitis and invasive candidiasis in newborns with ELBW;

Regimen C: targeted ABT. Targeted ABT is used if a mother has flora that is resistant to the drugs of the initial antibiotic therapy regimens "A" and "B" and/or after receiving the results of a microbiological examination of a newborn with determined sensitivity of microorganisms to systemic antimicrobial drugs (ATC code J).

In case of absence of sensitivity of the isolated pathogens to systemic antibacterial drugs (ATC code J01) of the initial regimen, it is necessary to change to systemic antibacterial drugs (ATC code J01), the sensitivity to which was revealed, or switch to local protocols taking into account the microbiological monitoring of the department where the patient stays.

In case of an increase in laboratory activity, as well as in case of a suspected nosocomial infection secondary to the conducted starting therapy, it is recommended to study the patient's biological material from all available loci, a microbiological (culture) blood test for sterility is mandatory, after which it is necessary to correct the ABT.

The duration and strategy of ABT are determined in each case individually and depend on the severity of the child's condition and the normalization of clinical, laboratory and instrumental data. When prescribing ABT, instructions for drug use shall be followed. If it is necessary to prescribe an antibacterial drug in accordance with the sensitivity of the isolated microflora for vital indications outside the instructions for human use (off-label), it is recommended to conduct a medical panel/consultation and obtain an informed consent from the patient's legal representative.

Pathogenetically justified intensive therapy for a newborn with IPP is carried out in accordance with clinical/methodological recommendations depending on the existing comorbid disease/condition (normalization of acid-base composition, correction of respiratory and hemodynamic disorders, etc.) [18, 20, 33, 34, 88, 113].

Symptomatic therapy includes the administration of drugs depending on the clinical manifestations of the infectious process (hemostatic, anticonvulsant, sedative, etc.).

Early start of enteral nutrition is recommended (preference is given to breast milk); according to indications, total parenteral nutrition, partial parenteral nutrition, feeding with breast milk substitutes, including adapted milk formulas is performed [52, 73, 123, 131].

The therapeutic and protective regimen involves creating optimal conditions for newborns nursing. Depending on the severity of a condition, a newborn with a suspected IPP should be transferred to the neonatal intensive care unit (NICU), intensive care unit (ICU) or neonatal pathology unit. A premature baby should be kept in a thermally neutral environment, sensory stimulation should be limited (protection from light, noise, touch), body temperature should be monitored depending on thermal regulation, and pain syndrome should be prevented.

Medical rehabilitation is carried out depending on the concomitant pathology and complications by specialized specialists (neurologist, ophthalmologist, etc.).

Prevention of perinatal-specific infection: timely detection and treatment of infectious diseases in a mother during pregnancy, vaccination of mothers [11, 12, 50, 54, 64, 125, 135].

Compliance with the rules and regulations of SanPiN 1.2.3685–21 (sanitary and epidemiological regime in obstetric and neonatal departments).

Treatment of newborns with a perinatal-specific infection is carried out in the 24-hour in-patient settings (NICU, ICU, department of pathology of newborns and premature babies, neonatal unit in children's hospitals).

Indications for patient discharge from the medical institution:

1) stabilization of the child's condition is achieved, no signs of organ and system failure;

2) normalization of inflammation markers;

3) cancellation of antibacterial therapy at least 24 hours before discharge with monitoring of the general blood test and its mandatory interpretation on the day before discharge;

4) absence of other contraindications to discharge.

The disease prognosis may vary, depending on the gestational age at the time of birth, the severity of the infectious process, its duration, and comorbidities. In extremely premature infants, immunocompromised patients who had a perinatal-specific infection, the risk of developing periventricular leukomalacia, retinopathy of prematurity, bronchopulmonary dysplasia, disability, or death increases.

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Вклад авторов. Все авторы внесли существенный вклад в разработку концепции, проведение исследования и подготовку статьи, прочли и одобрили финальную версию перед публикацией.

Источник финансирования. Авторы заявляют об отсутствии внешнего финансирования при проведении исследования.

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