

Premature birth. Successes and failures

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Abstract

5–18% of pregnancies end in premature birth, defined as birth before 37 weeks of gestation. Every year, 15,000,000 babies are born prematurely worldwide, of which more than 1,000,000 die due to complications associated with prematurity. Their contribution to neonatal and infant mortality is significant (70 and 36%, respectively). Premature birth is a syndrome characterized by many etiological factors, such as intra- and extrauterine infections, decreased excretion and decreased reception of progesterone, uterine overdistension, cervical factor, stress and a number of other, sometimes unknown, reasons. Over the past decade, some progress has been made in predicting and preventing spontaneous preterm birth. The main method for predicting and diagnosing the threat of premature birth is transvaginal ultrasound cervicometry in the second trimester of pregnancy (14–24 weeks). The length of the sonographically measured cervix is the most accurate prognostic criterion for assessing the risk of preterm birth, especially in pregnant women at risk (history of preterm birth). Vaginal administration of micronized progesterone reduces the risk of preterm birth in women with a short cervix. Diagnosis is based on taking into account clinical symptoms, cervical length and biochemical tests that determine placental proteins. Hospitalization in a perinatal center or level III institutions, which include intensive care units and the second stage of nursing newborns, serves as the basis for the effective organization of medical care for premature birth. When indications for surgical delivery are indicated, preference should be given to a cesarean section with the extraction of a low-weight fetus in the entire amniotic sac. The article also reflects the contribution of the staff of the Department of Obstetrics and Gynecology named after prof. V.S. Gruzdev of Kazan State Medical University in solving the problem of premature birth.

Keywords: premature birth, prevention, diagnosis, delivery, cesarean section, extraction of the fetus in the whole amniotic sac.

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Currently, premature births (PBs, as defined by the World Health Organization [WHO]) are a pressing concern in medicine, public health, and society. Unfortunately, it remains far from resolved.

Annually, 15 million children are born prematurely worldwide [1]. PB-associated complications cause over 1 million deaths annually among these children [2]. Lifelong disabilities, such as learning difficulties and visual and hearing problems, are common among survivors. Moreover, long-term neurological complications occur in 25%–50% of cases [3]. Therefore, PBs contribute significantly to the infant mortality rate.

Among infants born at 22–24 weeks of gestation, 97%–98% die within a few weeks, with only 1% surviving without neurodevelopmental deficits. Those born at 24–25 weeks of gestation have a survival rate of 55%; however, only 32% do not have neurologic deficits at 18–22 months of age [4].

Global problems are investigated by scientists and practitioners of various disciplines. As ob-

stetricians and gynecologists, we focus on preventing, predicting, and treating PBs. Meanwhile, pediatricians, neonatologists, and resuscitators are dedicated to aiding children born prematurely, or “preterm.”

This raises the philosophical question of whether interventions are necessary in such situations. For centuries, thousands of exceptionally talented individuals with low or critical bodyweight have been born. They survived without medical assistance because of its unavailability at the time. Many of these individuals became major contributors to fields including science, public and political affairs, and culture. Thus, they managed to thrive despite nature’s selection.

Several individuals have significantly affected the development of society and human history. These individuals include Leonardo da Vinci, Albert Einstein, Charles Darwin, Nicolaus Copernicus, Wolfgang Amadeus Mozart, Salvador Dali, Alexander Sergeyevich Pushkin, Napoleon Bona-

parte, Alexander Suvorov, Winston Churchill, and numerous others.

In addition to philosophical concerns, medical and social issues exist. During the XIV Congress of the European Association of Gynecologists and Obstetricians (EAGO), Litte disclosed the findings of a study affirming David Barker's theory that low birthweight was the primary risk factor in reducing life expectancy and decreasing its quality (EAGO, Grenada, 1999) [5].

Despite the emergence of new medical technologies and drugs, the number of PBs is not decreasing but tends to increase [6].

In Russia, 4,943,600 children were born between 2017 and 2019. Of these children, 285.7 thousands were born prematurely, making up 5.8% of the total number of births [7].

PB is the primary reason behind neonatal and infant mortality and child morbidity and disability. According to the WHO, premature infants account for 70% of infant mortality [8].

PBs occur between 22 and 36 weeks and 6 days of gestation when the baby has a bodyweight of 500–2500 g and a length of 25–45 cm. Premature babies often have conditions caused by lung immaturity, respiratory distress syndrome (RDS), intra-ventricular hemorrhage, lack of thermoregulation, maladaptation of metabolic processes, traumatic delivery, and other factors [9]. Obstetric factors must be thoroughly investigated, and suggestions should be offered to mitigate the medical reasons for negative consequences. Various subtypes of prematurity exhibit varied risk profiles, underscoring the requirement for diverse professional approaches (Fig. 1).

The classification of PBs based on gestational age is as follows:

- Extremely PBs: 22–27 weeks and 6 days of gestation
- Early PBs: 28–30 weeks and 6 days of gestation
- PBs: 31–33 weeks and 6 days of gestation
- Late PBs: 34–36 weeks and 6 days of gestation

Despite studies, discoveries, and attempts to implement the obtained data, PBs remain to account for 10% of all births, as reported by the WHO [10]. In Europe, the frequency is slightly lower, ranging from 5%–7% [10].

The causes of PBs are varied and largely understudied. The role of infectious factors, hormonal imbalances (including progesterone deficiencies and other endocrinopathies), and certain pregnancy complications has been established [1, 2].

In the 1990s, our involvement in these issues commenced. Despite being unconventional, we focused on the establishment of a neonatal intensive care and resuscitation unit in the New Maternity

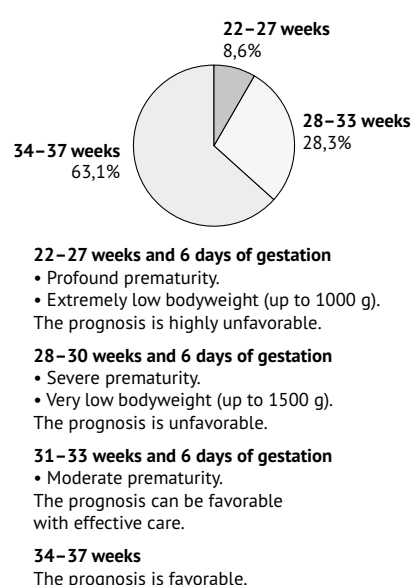


Fig. 1. Structure of premature births in Russia (2017) [5]

Hospital No.1 in Kazan. This hospital was constructed using the standard protocol, which did not provide for a department specializing in neonatal care, resuscitation, equipment, and staffing for such a unit. In the past, premature baby delivery was primarily conducted by obstetric research institutions and children's hospitals. The transportation of an unhealthy newborn negatively affects their survival and subsequent development, as demonstrated by the foreign experience and our domestic pediatric neonatologists' practices [4].

Neonatal and infant mortality rates were high during that era, particularly in Kazan, where >100 newborns die annually. Prematurity was the cause of death in 70% of these cases.

Establishing a neonatal intensive care and resuscitation unit in a typical maternity hospital is a challenging task. However, as the chief physician of the hospital and head of the Department of Obstetrics and Gynecology No.2 at Kazan State Medical Institute, I facilitated the solution. A good understanding of the issue, effective collaboration with Russian experts, and personal connections with relevant specialists helped in presenting this proposal persuasively. I.S. Abdullin, Deputy Minister and Head of the Kazan Health Department, provided invaluable personal support, along with G.A. Bardina.

Since then, PBs have become one of the scientific and methodological areas for the department. The maternity hospital and clinic have become the central location for PBs in the city. The Department of Pediatrics, led by Professor V.P. Bulatov, along with Dr. Sci. (Med.) L.K. Fazleeva and Cand. Sci. (Med.) N.H. Gabitova, were also engaged in this study.

The following obstetric factors are practically and scientifically significant: risk prediction, prevention, early identification of PB onset, strategies for prolonging gestation, delivery concerns, and quality of neonatal resuscitation and care. These factors enhance outcomes, prioritize the child, and support the well-being of the mother and her family. Furthermore, the psychological repercussions are significant given that the birth, illness, or death of a premature infant can be a severe traumatic experience.

In the ensuing years, a rudimentary framework for efficient PB care emerged. This included addressing various concerns, such as predicting and averting hazards, avoiding forceful delivery techniques, boosting neonatal care, and enhancing resuscitation.

In 2007, members of the department participated in a multicenter study conducted in Russia entitled, "Preterm Infants Undergoing Resuscitation: Analysis of Obstetric Tactics" [11]. The results indicated that severe prematurity rates at birth were influenced by both delivery timing and quality of pregnancy and labor management. The main causes were identified as follows:

- Various centers have reported the underestimation of risk factors and inadequate prevention measures in the outpatient monitoring of pregnant women at high risk of PB, ranging from 40%–80%.
- Inadequate tocolytic therapy upon admission to the maternity hospital (54%–80%) helps prolong pregnancy and prepare the fetal lungs. However, 25% of pregnant women referred to the maternity hospital with life-threatening PB did not receive any prophylaxis for neonatal RDS, and 37.5% received an incomplete course of glucocorticoid therapy.
- Lack of anesthesia upon childbirth (90%)
- Failure to comply with the principles of gentle delivery (70%)

The study was conducted across various cities in the Russian Federation with well-organized obstetric care services and effective interaction with universities and research institutes. The results revealed common shortcomings in the system. Based on the collected data, the study identified the primary areas to be studied and the implementation of effective labor and delivery practices. Thus, the unresolved and controversial issues related to the problem were explored.

Prediction and prevention

At present, the condition of the cervix is widely accepted to significantly affect pregnancy outcomes. Studies conducted in the USA, Italy, UK, and Brazil (Carlo Di Renzo, Roberto Romero, Sonia Hassan, Eduardo Borges da Fonseca, etc.) have

demonstrated that a cervical length of <25 mm greatly increases the likelihood of early pregnancy termination [12]. Transvaginal ultrasonography at 20 weeks of gestation can accurately predict this risk. The risk of PB is heightened by factors such as a previous history of PBs, smoking, urogenital infections, and other risk factors. This approach identifies expectant mothers at high risk for PB and facilitates the selection of appropriate therapeutic interventions.

Studies into the potential causes of asymptomatic cervical shortening during pregnancy led to the concept of "progesterone deficiency." According to a Cochrane systematic review that comprised 36 studies involving 8,523 women and 12,515 newborns, gestagen therapy in the high-risk group was linked to a reduced risk of perinatal and neonatal mortality, PB, and delivery of infants weighing $\leq 3,500$ g. In addition, administering progesterone preparations to women with a history of spontaneous PB led to an average extension of the duration of gestation by 4.5 weeks [13].

Among hormonal support options, European and Russian experts suggest intravaginal application of micronized progesterone during the latter half of pregnancy. Nevertheless, the effectiveness of such measures falls short of 100%. Multifactoriality and unclear etiology limited the selection of a precise intervention to prevent premature uterine contractility.

For a long time, the identification of PB has been an unresolved question. Only approximately 20% of pregnant women with suspected PB deliver early. Often, PB has no specific manifestations before the development of active uterine contractility. This leads to repeated hospitalizations and prescriptions of unnecessary therapy, making it the most typical example of iatrogenesis in obstetrics [5].

In 2008, a study conducted at the All-Russian Scientific and Practical Seminar "Reproductive Potential of Russia Versions and Controversies" reported the findings of 900 cases where pregnant women with a referral diagnosis of threatening PB were refused hospitalization. Despite examinations at the emergency room that included ultrasonography, cervicometry, and fetal cardiotocography, the diagnosis was not confirmed. The women were then offered the option of continuing follow-up at the antenatal clinic. Subsequent analysis revealed that only nine of the patients were admitted to the maternity hospital with different diagnoses and only one with PB. Consequently, the problem of preventing overdiagnosis solely based on complaints persists, including the possibility of outpatient doctors hospitalizing patients as a form of insurance.

At present, available practical tests detect placental proteins. These tests identify such proteins in vaginal contents upon the onset of structural changes in the uterus, which precedes the beginning of labor. In 2008–2010, researchers from the Department and Clinic of Maternity Hospital No. 1 of the City Clinical Hospital No. 7 in Kazan assessed the sensitivity and specificity of various tests. The study findings were disseminated through several peer-reviewed journals and presented at multiple scientific and practical conferences [14, 15]. These results were used in the development of clinical guidelines and treatment protocols for PB.

In 2021, A.R. Akhmetgaliev, PhD, defended his thesis titled, “Differential approach to managing preterm labor in pregnant women.” The study demonstrated that the presence of placental alpha-microglobulin or phosphorylated protein-1 binding insulin-like growth factor predicted the likelihood of PB within 7–10 days [14]. The sensitivity of placental alpha-microglobulin detection among patients with threatened PB and intact fetal bladder was 84%, and its specificity was 90% [15].

Today, in clinical practice, the combined use of these tests and ultrasound cervicometry improves significantly PB diagnosis and determines indications for hospitalization and routing depending on gestational age. Tocolytic therapy is not recommended in the absence of objective signs of PB, such as cervical shortening according to ultrasound cervicometry and positive results of tests for PB.

Therapy

The principles of effective PB care are as follows:

- Accurate diagnosis
- Prescription of therapy aimed at suppressing or weakening premature contractions (tocolytic therapy, or tocolysis)
- Prescription of a short course of glucocorticoids (dexamethasone or betamethasone) to accelerate the maturation of the fetal lung surfactant (neonatal RDS prevention)
- Referral to a group II–III perinatal center or a maternity hospital with a neonatal intensive care unit

Obstetrician-gynecologists primarily aim to extend pregnancy based on three specific goals. The first and most desirable goal is to postpone fetal delivery until 34–36 weeks of gestation when the prognosis for fetal health and survival is generally favorable with quality resuscitative care. The second goal is to delay delivery by 48–72 h to implement measures that prevent neonatal RDS. The third goal is to facilitate higher-level hospital transfer for women experiencing PB.

After years of in-depth research and adherence to guidelines from various professional foreign associations, the clinical guidelines for PB, which were developed by the Russian Society of Obstetricians and Gynecologists and the Association of Obstetric Anesthesiologists and Resuscitators, now include the following drugs for tocolysis. Nifedipine, a slow calcium-channel blocker, and atosiban, a drug that blocks oxytocin receptors, are recommended as the first-line tocolytic therapy. Hexoprenaline, belonging to the sympathomimetic group, and nonsteroidal anti-inflammatory drugs such as indomethacin, are recommended as second-line tocolytic agents [4].

We participated in both a multicenter clinical trial and an initiative study examining the use of the domestic analog of atosiban in PB. The drug demonstrated significant efficacy when administered promptly. The treatment terms resulted in delayed pregnancies and prevented neonatal RDS. The term extension allowed for 58% of women to prolong their pregnancy up to 36–38 weeks [16].

RDS prevention is the primary objective of prescribing tocolytic therapy. RDS is a prevalent and severe condition during the early neonatal stage. Premature babies are vulnerable to RDS, with mortality rates at 25%, and this number reaches 80% for babies born at 22–28 weeks of gestation. Therefore, a brief course of glucocorticoid therapy (48 h) is highly recommended for mothers between 24–33 weeks of gestation. Unfortunately, this task remains unsolved because of objective reasons such as untimely seeking medical help and subjective reasons such as failure to comply with clinical recommendations, as indicated by a multicenter study [11] and ongoing monitoring in medical organizations within the Republic of Tatarstan and the Volga Federal District. The analysis of infant mortality of perinatal causes indicates the lack of RDS prophylaxis in the majority of observations between 24 and 33 weeks [11].

Delivery

The optimal delivery method for neonates remains controversial. According to [4], cesarean section should not be the preferred method because it is associated with an increased risk of neonatal complications in infants born between 24 and 28 weeks and those with breech presentation up to 33 weeks. Natural birth is considered more favorable after 34 weeks of gestation, provided that all requirements for gentle delivery are in place, such as intrapartum tocolysis, appropriate anesthesia, second stage without perineal protection, and involvement of a neonatologist-anesthesiologist. Birth trauma, which is the most significant outcome of PB,



Fig. 2. Cesarean section with the retrieval of the first twin fetus in the fetal bladder

occurs seven times more frequently in PB than in full-term labor.

Although cesarean section decreases the risk of fetal trauma, it does not eliminate it entirely. In 2006, our team developed a technique for performing cesarean sections that involves extracting a low birthweight fetus while still in the fetal membranes (Fig. 2). This method was implemented to enhance perinatal outcomes.

This operation, proposed by Prof. V. E. Radzinsky based on experience, aims to preserve the fetal bladder's integrity while performing uterine incisions. Then, the newborn is extracted within the membranes and transferred to the neonatal resuscitation table. Subsequently, the membranes are opened.

F.I. Fatkullin, the head of the Obstetrics Department at Maternity Hospital No. 1 in Kazan, examined 80 newborns delivered between 28 and 36 weeks of gestation using the “copy-pair” technique. The initial findings suggest that cesarean delivery with complete removal of the fetus in the intact fetal bladder was beneficial [17]. The analysis of clinical and specialized research revealed variations in the neurological status of neonates in the main group compared with the control group. The differences were observed in the reduction of hemorrhage frequency and severity, severity of cerebral ischemia, and perinatal injuries of the central nervous system [17].

The cesarean section technique with the extraction of the fetus with an intact fetal bladder was proposed as the preferred operation for PB at the IV Congress of Obstetricians and Gynecologists of Russia and was included in the Russian clinical recommendations “Premature Labor” (treatment protocol) in 2020 [4] and in the clinical recommendations on cesarean section in 2014 and 2021 [18]. Many maternity hospitals and perinatal centers now use this technique.

In 2015, we proposed using intact fetal bladder retrieval surgery for multiple pregnancies with low birthweight fetuses, which are typically terminated early. A study, with participation by N.R. Akhmadeev, confirmed the benefits of this approach over traditional cesarean section [19–21].

In 2016, the Russian experience of using intact fetal bladder retrieval surgery for PB was reported by V.E. Radzinsky with our participation at the XXV European Congress of Perinatal Medicine, and the article was published in “The Journal of Maternal-Fetal and Neonatal Medicine” [22].

Despite our success in researching, developing, and implementing effective medical care practices for PB, the foremost priority remains providing adequate resuscitation care to the newborn. This problem can be resolved by transferring both the pregnant woman and the fetus to a perinatal center or a level III facility that offers an intensive care unit and has a second-stage neonatal care unit. Current protocols recommend measures for diagnosing threatening PB, using tocolytic therapy, and preventing neonatal RDS. These measures focus on ensuring appropriate routing and transportation of pregnant women, who should be accompanied by a midwife for delivery placement. Transportation to the nearest obstetric facility should be only initiated once regular labor activity ensues.

The implementation of a three-tier medical care system, construction of modern perinatal centers in regions, and development of evidence-based medicine-driven clinical recommendations significantly decreased the infant mortality rate in Russia to the lowest recorded historical rate of 4.5% (Rosstat, 2022), which is below the European average.

Unresolved questions regarding etiology exist because all causes must be eliminated to influence PB. PB is a complex of pathologic processes that lead to the common pathway of labor induction. Although all the factors examined, including the most crucial one of having a PB history, reflect the risk, they do not explain the mechanism.

Human childbirth exhibits unique molecular, genetic, and behavioral characteristics. Despite this uniqueness, an ideal animal model for studying childbirth causes remains elusive; as a result, key factors remain unresolved.

Prospects

PB is of immense medical, social, and economic significance, drawing the attention of diverse scholars. The implementation of a personalized

approach to the investigation of the root causes and prediction of outcomes may reduce task complexity. Despite this, resolving PB remains a challenging and time-consuming undertaking.

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