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ABSTRACT

of the dissertation for the degree of Doctor of Philosophy

DIAGNOSIS AND PROGNOSTIC ASSESSMENT OF CONGENITAL ANOMALIES IN CHILDREN UNDER 1 YEAR OF AGE IN CRITICAL CONDITION

Speciality: 3220.01 – "Pediatrics"

Field of science: Medical Sciences

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GENERAL DESCRIPTION OF THE WORK

Relevance of the research: Congenital anomalies are pathological conditions arising during prenatal development as a result of disturbances in embryogenesis or morphogenesis, characterized by structural, functional, or genetic-chromosomal defects of organs and systems[1]. According to epidemiological data, congenital anomalies are detected in approximately 6% of newborns[2], account for 15–30% of pediatric hospitalizations[3], and are responsible for 15.5% of neonatal mortality cases[4].

In Azerbaijan, a statistical analysis presented in the UNICEF report entitled "Children's Environmental Health Assessment in Azerbaijan" demonstrated that the incidence of congenital anomalies among children aged 0–13 years remained relatively stable over the last five years, reaching approximately 42.39–43.2 cases per 10,000 population during 2017–2022. Furthermore, in 2021, congenital anomalies accounted for 11.7 deaths per 10,000 live births among infants under one year of age, representing one of the leading causes of infant mortality[5]. These findings indicate that congenital anomalies constitute not only a major medical concern but also a significant socio-economic burden.

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[1] National Congenital Anomaly and Rare Disease Registration Service (NCARDRS): [Electronic resource]. – London: NHS Digital, 2025. – URL: https://digital.nhs.uk/ndrs/about/ncardrs

[2] Congenital disorders: [Electronic resource] / World Health Organization. – Geneva, – 2023. – URL: https://www.who.int/health-topics/congenital-anomalies#tab = tab_1

[3] Alanazi, A.F.R. Trends of Hospital Admissions Due to Congenital Anomalies in England and Wales between 1999 and 2019: An Ecological Study / A.F.R.Alanazi, A.Alenezi, M.Alshammari [et al.] // International Journal of Environmental Research and Public Health. – 2021. – 18 (22). – 11808. – DOI: https://doi.org/10.3390/ijerph182211808

[4] Dursun, A. Distribution of congenital anomalies in a neonatal intensive care unit in Turkey / A.Dursun, A.Zenciroglu, N.Hakan [et al.] // Journal of Maternal-Fetal and Neonatal Medicine. – 2014. – 27 (10). – p. 1069–1074. – DOI: https://doi.org/10.3109/14767058.2013.847420

[5] Children's environmental health assessment in Azerbaijan: [Electronic resource] / comp. by UNICEF. – Baku: UNICEF Azerbaijan, – 2023. – 69 p. – URL: https://ceh.unicef.org/events-and-resources/knowledge-library/childrens-environmental-health-assessment-azerbaijan

Although the incidence of congenital anomalies in children and their variability according to sex and gestational age have been reported, the role of these conditions in the development of critical illness during the neonatal period and their impact on clinical outcomes have not yet been fully elucidated[6]. In Azerbaijan, the high prevalence of consanguineous marriages, the persistence of adolescent pregnancies, and the incomplete coverage of antenatal screening programs among pregnant women are considered major factors contributing to the increased frequency of congenital anomalies[7]. Nevertheless, the clinical outcomes and mortality risk associated with congenital anomalies leading to critical conditions in the neonatal period remain insufficiently investigated in our country.

According to the classification of the World Health Organization, congenital anomalies are divided into structural and functional types; structural anomalies include malformation, deformation, disruption, and dysplasia and are further classified into major and minor categories. Major anomalies increase the risk of neonatal mortality, disability, and the need for medical intervention, and include cardiovascular anomalies, neural tube defects, orofacial defects, and others. Although minor anomalies are generally not life-threatening, their early detection and clinical evaluation are of considerable importance due to their potential association with more severe pathologies[8]. According to contemporary

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[6] Egbe, A. Congenital Malformations in the Newborn Population: A Population Study and Analysis of the Effect of Sex and Prematurity / A.Egbe, S.Uppu, S.Lee [et al.] // Pediatrics and Neonatology. – 2015. – 56 (1). – p. 25–30. – DOI: https://doi.org/10.1016/j.pedneo.2014.03.010

[7] Mammadzade G.T. Congenital malformations among newborns in the Republic of Azerbaijan (epidemiology, diagnostics): abstract of the dissertation for the degree of Doctor of Medical Sciences. – Baku, 2022. – 60 p. – (in Azerbaijani). – URL: https://aak.gov.az/upload/dissertasion/tibb_elml_ri/avtoreferat_az_Gulnara_Mamedzade.pdf

[8] Birth Defects Surveillance: A Manual for Programme Managers. Second edition: [Electronic resource] / World Health Organization; Centers for Disease Control and Prevention; International Clearinghouse for Birth Defects Surveillance and Research. – Geneva: WHO, – 2020. – 248 p. – URL: https://archive.cdc.gov/www_cdc_gov/ncbddd/birthdefects/surveillancemanual/resource-library/Birth-Defects-Surveillance-A-Manual-for-Programme-Managers-2020Manual-P.pdf

clinical and genetic studies, the etiology of major congenital anomalies remains unknown in approximately 40–50% of cases, while 20–25% are attributed to multifactorial causes, 7–8% to monogenic disorders, 6–7% to chromosomal abnormalities, and nearly 6% to teratogenic factors. Advances in genomic analysis in recent years have contributed to increased detection rates of monogenic and chromosomal congenital anomalies[9].

In congenital anomalies, particularly in critical conditions, the objective assessment of the clinical status and prognosis during the neonatal period is of paramount importance. International intensive care scoring systems such as SNAPPE-II (Score for Neonatal Acute Physiology with Perinatal Extension-II), CRIB (Clinical Risk Index for Babies), NTISS (Neonatal Therapeutic Intervention Scoring System), and PRISM III (Pediatric Risk of Mortality III) are employed for the evaluation of critical conditions; these scales enable an objective assessment of disease severity and mortality risk by taking into account physiological parameters, risk factors, and intensive care interventions. Furthermore, the MINT (Mortality Index for Neonatal Transportation) scale is utilized to determine prognostic risks at the time of patient discharge.

In recent years, the clinical assessment of critical conditions has expanded to include biomarker-based approaches, involving the combined evaluation of lactate, NT-proBNP (N-terminal pro brain natriuretic peptide), I-FABP (intestinal fatty acid-binding protein), and BDNF (brain-derived neurotrophic factor) levels alongside clinical indicators. However, a review of the literature revealed no studies evaluating the application and clinical-prognostic value of these biomarkers in patients with congenital anomalies.

Reliable prognostic criteria for assessing the risk of mortality and complications in critical conditions associated with congenital anomalies in children under one year of age remain insufficiently

[9] Dysmorphology. Chapter 102: [Electronic resource] / A.Wynshaw-Boris, L.G.Biesecker (eds.). – Philadelphia: Elsevier, – 2020. – URL: https://elsevier-elibrary.com/contents/fullcontent/15188720/epubcontent_v2/OEBPS/B9781437707557001020.htm

established. Therefore, identifying reliable predictors for the clinical course and outcomes of critical conditions in infants with congenital anomalies continues to represent a relevant scientific and clinical challenge.

Object and subject of the research. The study population consisted of 1,256 critically ill children diagnosed with congenital anomalies, irrespective of gestational age and birth weight. A control group of 53 apparently healthy children was also included.

The enrolled patients were assessed using standardized clinical severity scoring systems and were subsequently categorized according to the classification of congenital anomalies. Biomarker levels in blood samples were determined in 230 critically ill patients with congenital cardiovascular, gastrointestinal and abdominal wall defects, and central nervous system anomalies, and were compared with the corresponding clinical parameters.

Based on the obtained clinical and laboratory findings, prognostic criteria were developed to predict disease course and outcomes in critically ill children under one year of age with congenital anomalies.

The purpose of the study. The aim of the study was to perform a structural analysis of congenital anomalies in critically ill children under one year of age, evaluate the severity of critical illness, and develop prognostic criteria based on system-specific biomarkers associated with the affected organs and systems.

Research Objectives.

1. To determine the prevalence of congenital anomalies among children under one year of age admitted to the intensive care unit and to analyze, by organ system, the congenital anomalies leading to critical conditions;

2. To evaluate the severity of critical conditions in children under one year of age with congenital anomalies using different clinical severity scoring systems and to perform a comparative analysis of their association with prognosis;

3. To determine the diagnostic and prognostic significance of NT-proBNP and blood lactate and to assess the correlation between

these biomarkers in critically ill children under one year of age with congenital cardiovascular anomalies;

4. To investigate the diagnostic and prognostic value of the I-FABP biomarker and its clinical utility in the assessment of outcomes in critically ill children under one year of age with gastrointestinal anomalies and anterior abdominal wall defects;

5. To determine the diagnostic significance of the BDNF biomarker and to assess its association with clinical outcomes in critically ill children under one year of age with congenital nervous system anomalies;

6. To conduct a statistical analysis of prognostic criteria for critical conditions in children under one year of age with congenital anomalies and to develop predictive models for prognostic assessment in this patient population.

Research methods.

The study was conducted at the Scientific Research Institute of Pediatrics named after K.Y. Farajova (SRIP) between 2019 and 2022 and consisted of retrospective and prospective phases.

A total of 1,309 children under one year of age were included in the analysis. Of these, 1,256 were critically ill patients diagnosed with congenital anomalies, while 53 were practically healthy children of the same age group who constituted the control group.

The structural characteristics, clinical status, and critical course of patients with congenital anomalies were systematically evaluated. Structural analysis included the cause of admission to the intensive care unit, age, mode of delivery, body weight, gestational age, need for mechanical ventilation and surgical intervention, complications, and duration of stay in the intensive care unit.

The severity of the critical condition was assessed using the international scoring systems NTISS, SNAPPE-II, CRIB, MINT, and PRISM-III.

To ensure objective evaluation of the patients' condition, biochemical blood analyses were performed, and biomarker levels of NT-proBNP, I-FABP, and BDNF were determined according to the affected organs and systems.

As a result, prognostic criteria for critical conditions in children under one year of age with congenital anomalies were identified, and statistical formulas for outcome prediction were developed.

Main propositions of the Dissertation for Defense:

1. During the study period (2019–2022), congenital anomalies were identified in an average of 15.2% of patients under one year of age treated in the intensive care unit, with cardiovascular and gastrointestinal anomalies being the predominant conditions among these patients;

2. The SNAPPE-II and MINT scoring systems used in our study were informative for assessing the severity of critical illness and predicting fatal outcomes in neonates with congenital anomalies; however, these scales do not account for important factors such as the type and severity of the anomaly or indications for surgical intervention;

3. In critically ill infants with congenital heart defects (CHD), elevated blood NT-proBNP levels indicated the significant diagnostic value of this biomarker. Cases with fatal outcomes demonstrated statistically significantly higher blood lactate levels, and a positive correlation was identified between NT-proBNP and lactate concentrations.

4. In patients with congenital gastrointestinal anomalies and abdominal wall defects, levels of I-FABP, a biomarker of intestinal epithelial injury, were elevated compared with those of healthy children. This increase was statistically significant particularly in patients who developed complications and required surgical intervention;

5. In patients under one year of age with central nervous system (CNS) anomalies, decreased blood levels of the neuroprotective protein BDNF indicated the potential utility of this biomarker as a diagnostic indicator in CNS anomalies;

6. Based on clinical and laboratory parameters, as well as the results of various clinical scoring systems, a prognostic equation was developed for critically ill children under one year of age with diagnosed congenital anomalies using a neural network model and logistic regression analysis. The developed model demonstrated high

sensitivity and reliability for prognostic assessment in patients with congenital anomalies.

Scientific novelty of the study:

- International clinical scoring systems (NTISS, SNAPPE-II, CRIB, MINT, and PRISM-III) were applied for the evaluation of critical conditions in children under one year of age with congenital anomalies admitted to the intensive care unit, and the diagnostic and prognostic utility of these scales was established in this patient population;

- The diagnostic and prognostic value of biomarkers corresponding to the affected organ systems, including NT-proBNP, I-FABP, and BDNF, was determined for assessing disease severity in critically ill children under one year of age with congenital anomalies; moreover, a correlation between blood lactate values and NT-proBNP levels was identified in congenital cardiovascular anomalies;

- A prognostic equation was developed for critically ill children under one year of age with diagnosed congenital anomalies using a neural network model and logistic regression analysis based on clinical, laboratory, and functional parameters, as well as the results of clinical scoring systems, and its predictive accuracy for survival and mortality was established.

Practical significance of the study:

- The frequency and system-specific distribution of congenital anomalies in critically ill children under one year of age were investigated. These findings are of practical importance for improving diagnostic and therapeutic strategies, as well as for optimizing screening programs and healthcare planning.

- The applicability of the NTISS, SNAPPE-II, CRIB, MINT, and PRISM-III scoring systems for assessing disease severity and prognosis in patients with congenital anomalies treated in the intensive care unit was investigated, and the prognostic informativeness of these scales was evaluated.

- Retrospective and prospective analyses of treatment outcomes in patients with congenital anomalies admitted to the intensive care unit enabled the identification of factors influencing prognosis.

- The use of biomarkers, including NT-proBNP, I-FABP, BDNF, and blood lactate levels, for assessing the severity of critical illness according to the affected organ systems in children under one year of age treated in the intensive care unit was investigated, and their diagnostic and prognostic value was evaluated.

- Based on the analysis of clinical data and the experience gained, a prognostic equation was developed for children under one year of age admitted to the intensive care unit to facilitate the timely detection of congenital anomalies, accurate assessment of disease severity, and selection of appropriate treatment strategies; the accuracy of this equation for prognostic assessment was subsequently validated in clinical practice.

Published works. Based on the findings of the study, a total of 19 scientific publications, including 13 research articles and 6 conference abstracts, were published.

Institution Where the Dissertation Was Conducted. The dissertation research was carried out at the Neonatal Resuscitation and Intensive Care Unit of the Scientific Research Institute of Pediatrics named after K.Y. Farajova, the Neonatal Intensive Care Unit of the Department of Pregnancy Pathology at the Republican Clinical Hospital named after Academician M.A. Mirgasimov, and the ELLAB Diagnostic Center.

Implementation of the Research Results. The results of the study have been implemented in the clinical departments of the Scientific Research Institute of Pediatrics named after K.Y. Farajova.

Structure and Volume of the Dissertation. The dissertation is presented in Azerbaijani and comprises 184 pages (204,600 characters). It is structured as follows: Introduction (12,950 characters), Chapter I (50,590 characters), Chapter II (24,530 characters), Chapter III (12,050 characters), Chapter IV (14,715 characters), Chapter V (10,960 characters), Chapter VI (35,150 characters), General Discussion/Conclusion (39,361 characters), Conclusions (2,870 characters), and Practical Recommendations (1,420 characters), as well as abbreviations, a bibliography, and appendices.

177 literature sources were used in the preparation of the dissertation. Of the literature sources used, 2 are in Azerbaijani, 8 are in Turkish, 2 are in Russian, 164 are in English and 1 is in Portuguese. The dissertation work consists of 38 tables, 16 graphs and 1 figure.

MATERIALS AND METHODS OF THE RESEARCH

The study was conducted between 2019 and 2022 at the Neonatal Intensive Care and Resuscitation Department of the Scientific Research Institute of Pediatrics, the Neonatal Intensive Care Unit of the Department of Pregnancy Pathology at the Academic M.A. Mirgasimov Republican Clinical Hospital, and the ELLAB Diagnostic Center. A total of 1,309 children were included in the study, comprising 1,256 critically ill children under one year of age diagnosed with congenital anomalies and 53 practically healthy children who served as the control group.

Children without congenital anomalies, those not in critical condition, patients with an intensive care unit stay of less than 24 hours, children older than one year, and newborns with anomalies prone to spontaneous regression were excluded from the study.

During the retrospective phase of the study, 522 children (39.9%) were enrolled between 2019 and 2020, whereas 787 children (60.1%), including both patient and control groups, were included in the investigation during 2021–2022. The examined children were stratified by age into neonates (first 28 days of life) and children aged 29 days to 1 year. Neonates were further subdivided into preterm and full-term infants, while children aged 29 days to 1 year were categorized into the following subgroups: 29 days to 6 months and 6 months to 1 year. All patients underwent comprehensive evaluation following admission to the intensive care unit and initial stabilization.

For the assessment of clinical status, children within the first 28 days of life were evaluated using the SNAPPE-II, NTISS, CRIB, and MINT scoring systems, whereas children aged 29 days to 1 year were assessed using the PRISM III scale. Laboratory investigations were performed at the Scientific Laboratory Department for

Diagnostic Research of the Scientific Research Institute of Pediatrics and at the ELLAB Diagnostic Center. The investigations included assessment of blood acid–base balance, as well as biochemical, serological, immunological, and metabolic panels. Serum levels of NT-proBNP, I-FABP, and BDNF were determined by enzyme-linked immunosorbent assay (ELISA) in patients diagnosed with congenital anomalies according to the affected organ systems.

Statistical analysis was performed using Microsoft Excel 2019 spreadsheets and the SPSS Statistics 26 software package. Depending on the distribution characteristics of quantitative variables, both parametric and non-parametric methods were applied. Intergroup comparisons were conducted using Student's t-test, the Bonferroni-adjusted t-test, the Mann–Whitney U test, and the Kruskal–Wallis test, whereas qualitative variables were compared using Pearson's chi-square test and Fisher- Snedecor test. Spearman's correlation coefficient was calculated to assess associations between variables, and receiver operating characteristic (ROC) analysis was performed to determine the diagnostic and prognostic value of biomarkers. Statistical significance was established at $p < 0.05$.

To predict disease severity and clinical outcomes in critically ill patients with congenital anomalies, multivariable logistic regression analysis was applied, and prognostic models were developed using backward and forward stepwise selection methods. Statistically significant variables were identified based on the Wald criterion, while optimal cut-off points were determined using ROC analysis. To improve prognostic accuracy, a neural network model based on supervised learning principles was implemented. Model performance was evaluated in terms of accuracy, sensitivity, specificity, and area under the curve (AUC), and compared with conventional statistical models.

RESULTS AND DISCUSSION

A total of 1,309 children were included in the study. Of these, 389 (29.7%) were born preterm (<37 weeks of gestation), while 920

(70.3%) were born at term (≥37 weeks of gestation). According to sex distribution, 811 (62.0%) were male and 498 (38.0%) were female.

During the study period (2019–2022), congenital anomalies were diagnosed in 1,256 (15.2%) patients under one year of age admitted to the Neonatal Resuscitation and Intensive Care Unit of the Scientific Research Institute of Pediatrics (Table 1).

Table 1
Prevalence of Congenital Anomalies by Years

Years	Total Hospital Admissions	NICU Admissions	Patients with anomalies	Prevalence (%)	Statistical Parametrs
2019	8,194	2,123	341	16.1%	EIF=0.54 95%CI: 0.44-0.63 F=14.910; p<0.001
2020	6,073	1,721	181	10.5%	
2021	8,207	1,991	297	14.9%	
2022	11,673	2,441	437	17.9%	
Total	34,147	8,276	1256	15.2%	

Note: EIF – effect influence factor; F – Fisher's criterion in analysis of variance; p – level of statistical significance.

According to age distribution, 921 patients (73.3%) were admitted to the intensive care unit within the first 28 days of life, 266 (21.2%) between 29 days and 6 months of age, and 69 (5.5%) between 6 months and 1 year of age. Congenital anomaly diagnosis was established antenatally in 51 children (4.0%), in the maternity hospital in 653 children (52.0%), and in the intensive care unit in 552 children (44.0%).

Analysis of the indications for admission to the intensive care unit demonstrated that 456 patients (36.3%) were admitted for conditions unrelated to congenital anomalies (including sepsis, jaundice, respiratory failure, and others), 94 patients (7.5%) were transferred from other healthcare facilities with suspected congenital anomalies, and 706 patients (56.2%) were admitted with a confirmed diagnosis of congenital anomalies. The diagnosis of congenital anomaly was ultimately verified in all cases.

Structural analysis revealed that 1,159 patients (92.3%) had structural abnormalities, 68 (5.4%) had functional abnormalities, and 22 (1.8%) had mixed-type abnormalities (structural + functional). According to clinical significance, anomalies were categorized as primary (main) anomalies in 1,065 patients (84.8%) and secondary (additional) anomalies in 191 patients (15.2%).

Multiple organ system involvement was observed in 219 patients (17.4%); among them, two systems were simultaneously affected in 195 patients, three systems in 23 patients, and four systems in 1 patient. In cases of multiple system involvement, the cardiovascular system (n=181; 82.6%; $p<0.001$), gastrointestinal system (n=110; 50.2%; $p<0.001$), and nervous system (n=60; 27.4%; $p<0.001$) were most frequently affected. Among critically ill patients, congenital heart defects accounted for the highest proportion (42.4%), followed by gastrointestinal anomalies (36.2%), nervous system anomalies (14.6%), syndromic pathologies (10.0%), and other congenital anomalies.

Among critically ill patients diagnosed with congenital anomalies, the duration of mechanical ventilation in 536 patients averaged 6±0.3 days (range: 1–41 days), while the average length of stay in the intensive care unit among all 1,256 patients was 10.9±0.3 days. Surgical intervention was performed in 520 patients (41.4%). The survival rate was 86.3%, whereas mortality was observed in 172 patients (13.7%).

The severity of critical conditions in patients diagnosed with congenital anomalies was assessed using different clinical scoring systems according to age group. Within the first 24 hours after stabilization in the intensive care unit, the SNAPPE-II, NTISS, CRIB, and MINT scoring systems were applied during the neonatal period, whereas the PRISM III scale was used in children aged 29 days to 1 year. Among 921 neonates diagnosed with critical congenital anomalies during the first 28 days of life, the mean scores were 18.6±2.7 for NTISS, 14.2±12.9 for SNAPPE-II, 4.6±2.4 for CRIB, and 6.9±3.2 for MINT.

The NTISS scale was additionally reassessed on days 7, 10–14, and 21–30 according to the duration of intensive care unit stay. Compared with the baseline value, a statistically significant decrease

in NTISS scores over time was observed (p<0.001, Wilcoxon test). This finding indicates that the NTISS scale is sensitive to changes in clinical condition.

Among critically ill neonates diagnosed with congenital heart defects (n=412), comparison according to gestational age demonstrated a statistically significant difference only for the SNAPPE-II scale (P_U<0.001). ROC analysis performed between survivors (n=331) and non-survivors (n=81) demonstrated high prognostic performance for all scoring systems, with the highest AUC values observed for the CRIB (AUC=0.788) and NTISS (AUC=0.784) scales (p<0.001) (Figure 1).

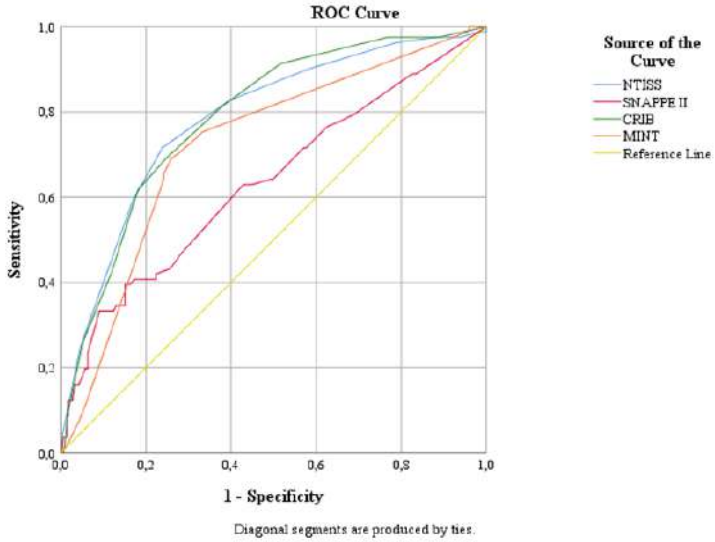


Figure 1 – ROC Analysis of Prognostic Scoring Systems for Survival and Mortality in Neonates with Cardiovascular System Anomalies

In the comparison of preterm (n=115) and full-term (n=282) neonates with gastrointestinal system anomalies, a statistically significant difference was observed only for the SNAPPE-II scale

(p<0.001). ROC analysis performed between survivors (n=330) and non-survivors (n=67) demonstrated that all evaluation scales had high prognostic value (p<0.001). The highest AUC values were identified for the CRIB (AUC=0.817) and NTISS (AUC=0.790) scales. Additionally, the clinical informativeness of the SNAPPE-II and PRISM III scales in determining disease severity and prognosis was confirmed (Figure 2).

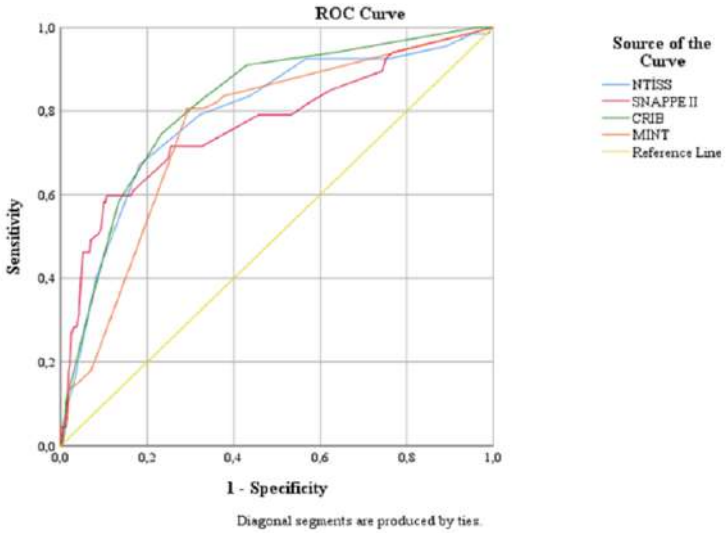


Figure 2 – ROC Analysis Between Survivor and Non-survivor Groups in Patients with Gastrointestinal System Anomalies

In comparisons according to gestational age, a statistically significant difference was identified only for the MINT scale in neonates with nervous system anomalies (p<0.05). ROC analysis performed between survivors (n=95) and non-survivors (n=9) with nervous system anomalies demonstrated that the MINT (AUC=0.727; p=0.025) and NTISS (AUC=0.816; p=0.002) scales had prognostic value. In contrast, the SNAPPE-II and CRIB scales did not demonstrate statistically significant prognostic significance in this subgroup (Figure 3).

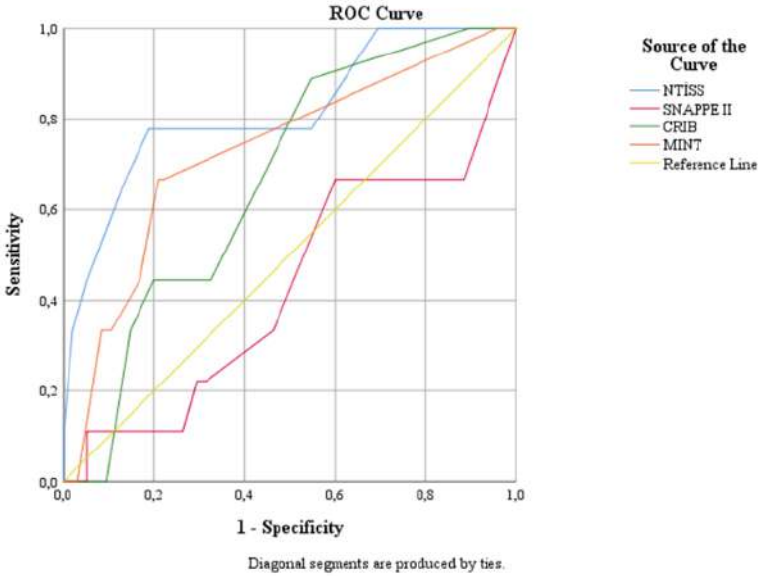


Figure 3 – ROC Analysis Between Survivor and Non-survivor Groups in Patients with Nervous System Anomalies

In the study, the diagnostic and prognostic value of NT-proBNP levels, as well as their correlation with blood lactate, were investigated in patients under one year of age diagnosed with congenital heart defects (CHD). NT-proBNP levels in 81 critically ill patients were compared with those of the control group (n=20). The mean NT-proBNP level in the study group was 12,811.6 ± 810.7 pg/mL (range: 445–40,163 pg/mL), whereas in the control group it was 135.6 ± 14.0 pg/mL (range: 78–320 pg/mL); the difference was statistically significant ($p < 0.001$).

Comparative analysis between patients with congenital heart defects and the control group demonstrated that NT-proBNP levels were significantly elevated across all major defect types compared with controls ($P_U<0.001$). NT-proBNP values observed in patients with congenital heart defects were further analyzed in the study (Figure 4).

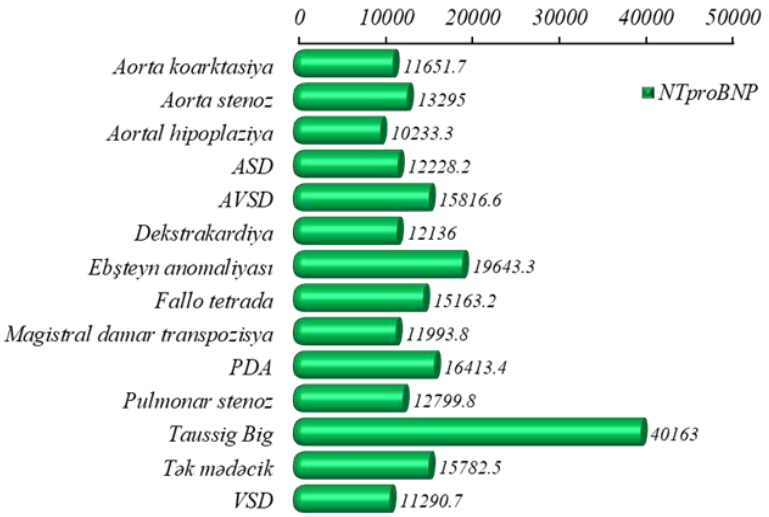


Figure 4 – Analysis of NT-proBNP Levels in Congenital Heart Defects

Comparative analysis of NT-proBNP and lactate levels according to age groups revealed the following findings (Table 2).

Table 2

Comparison of Lactate and NT-proBNP Levels Across Age Groups in Congenital Heart Defects (ANOVA/F-analysis)

Biomarker	Age group	Patients N	M	±m	Min	Max	P_F
Lactat (mmol/l)	1-28 day	253	6,0	0,2	1	22	0,943
	29 day - 6 month	68	5,9	0,5	1	20	
	6-12 month	11	6,3	1,1	2	14	
NT-proBNP (pg/ml)	1-28 day	55	13398,2	1095,5	445	40163	0,442
	29 day-6 month	21	10951,9	1082,4	3000	18500	
	6-12 month	5	12060,0	3438,4	1000	19800	

In the study, among patients diagnosed with congenital heart defects (CHD), the mean blood lactate level in the surviving group was 5.6±0.2 mmol/L, while the mean NT-proBNP level was 12,894.9±853.3 pg/mL. In patients with fatal outcomes, these values were 7.9±0.8 mmol/L and 11,903.8±2371.2 pg/mL, respectively. The findings demonstrated a statistically significant difference in blood lactate levels between the surviving and fatal outcome groups ($P_F<0.001$; $P_U=0.017$). (Table 2).

Furthermore, Spearman correlation analysis revealed a positive correlation between lactate and NT-proBNP levels ($\rho=0.333$; $P_U=0.003$).

The study demonstrated a statistically significant increase in NT-proBNP levels in children under one year of age with congenital heart defects (CHD) compared with the control group, indicating its diagnostic value. Blood lactate levels showed a statistically significant difference between survivors and patients with fatal outcomes and were therefore considered a prognostic marker. A positive correlation was identified between NT-proBNP and blood lactate levels.

In the study, I-FABP levels, considered a biomarker of intestinal epithelial injury, were analyzed in 99 children. Patients with congenital gastrointestinal anomalies and anterior abdominal wall defects (n=79) were compared with the control group (n=20). Among patients with gastrointestinal anomalies (n=74), the median I-FABP level was 2.3 ng/mL (2.0–2.5), whereas in the practically healthy group it was 0.80 ng/mL (0.65–0.88), with the difference being statistically significant ($p < 0.001$). In five patients with anterior abdominal wall defects, the mean I-FABP level was 2.3 ± 0.05 ng/mL and was significantly higher compared with the control group ($p < 0.001$).

A total of 101 anomalies were identified among the 74 patients with gastrointestinal anomalies, which may be explained by the simultaneous involvement of two or more parts of the gastrointestinal system in some patients (Table 3).

Table 3

I-FABP Levels in Patients with Gastrointestinal Anomalies and Abdominal Wall Defects

Gastrointestinal Anomalies and Abdominal Wall Defects	Number of Anomalies	I-FABP (ng/ml) Median (Q1–Q3)	p-value (P_U)
Hirschsprung's disease	28	1.90 (1.75–2.20)	< 0.001
Intestinal obstruction (total):	21	2.5 (2.4–2.5)	< 0.001
• Duodenal atresia	6	2.5 (2.4–2.5)	< 0.001
• Jejunal atresia	8	2.4 (2.2–2.45)	< 0.001
• Ileal atresia	5	2.5 (2.5)	0.001
• Colonic atresia	3	2.5 (2.40–2.50)	0.006
Meconium ileus	2	2.5	–
Ladd's syndrome	6	2.45 (2.4–2.5)	< 0.001
Meckel's diverticulum	2	2.25	–
Diaphragmatic hernia	15	2.40 (2.2–2.5)	< 0.001
Omphalocele	4	2.3 (2.2–2.4)	0.002
Gastroschisis	1	2.4	–
Control group (n=20)		0,80 (0,65-0,88)	

Note: P_U represents the statistical significance of differences in comparison with the control group indicators.

To evaluate the need for surgical intervention in patients with gastrointestinal anomalies and abdominal wall defects, I-FABP levels were compared between operated and non-operated patients. The median I-FABP level in patients who underwent surgery (n=69) was significantly higher than that in the non-operated group (n=10) (2.4 ng/mL vs. 1.90 ng/mL; $p<0.001$). ROC analysis demonstrated that I-FABP had the ability to discriminate patients requiring surgical intervention (AUC=0.825±0.049; 95% CI: 0.729–0.921; $p<0.001$), confirming the diagnostic potential of this biomarker (Figure 5).

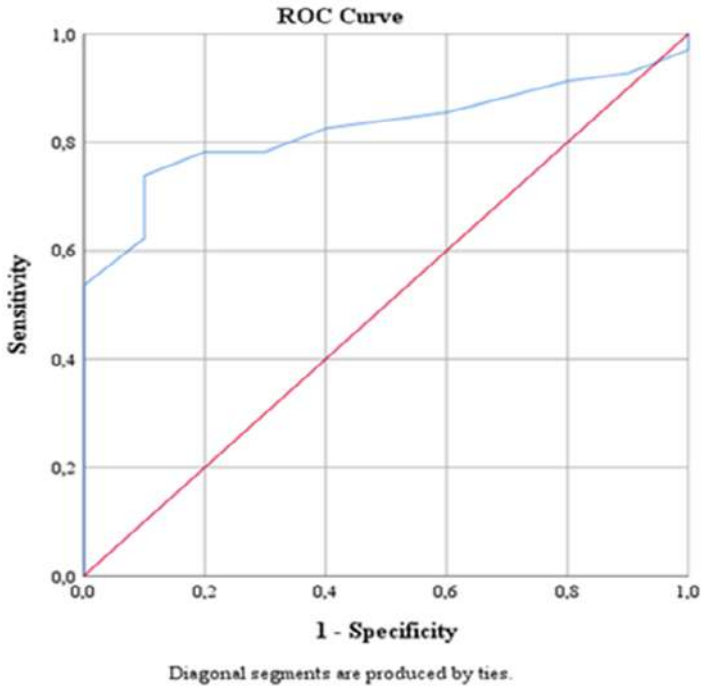


Figure 5 – Receiver Operating Characteristic (ROC) Analysis of I-FABP in Surgical and Non-Surgical Patients with Gastrointestinal Anomalies and Anterior Abdominal Wall Defects

In the comparison of patients with Hirschsprung disease, the median I-FABP level was 2.0 ng/mL in operated patients (n=19) and 1.9 ng/mL in non-operated patients (n=9); however, this difference was not statistically significant (p=0.383).

To evaluate the prognostic value of intestinal injury, ROC analysis was performed between survivors (n=69) and non-survivors (n=10), and the discriminatory ability of I-FABP levels was found to be statistically significant (AUC=0.698±0.065; 95% CI: 0.570–0.826; p=0.044) (Figure 6). Similar prognostic trends were also observed in patients with Hirschsprung disease and intestinal atresia, indicating the potential of I-FABP as a biomarker for predicting fatal outcomes.

However, due to the limited sample size, further studies involving larger patient populations are required to confirm these findings.

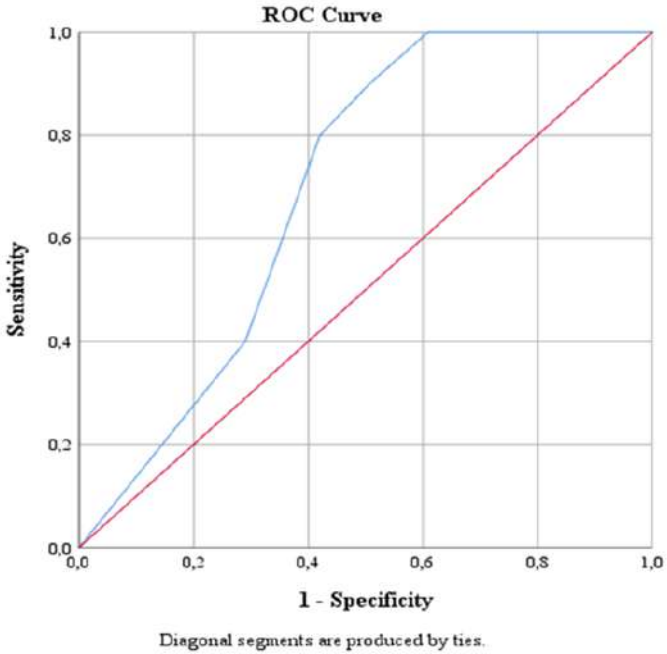


Figure 6 – Comparative Analysis of Survival and Mortality by I-FABP Levels in Patients with Intestinal Injury Associated with Gastrointestinal Anomalies and Anterior Abdominal Wall Defects

These results suggest that I-FABP may have clinical significance in predicting the severity of intestinal injury and the need for surgical intervention in patients with gastrointestinal anomalies and abdominal wall defects.

One of the aims of the study was to identify a potential deficiency of BDNF, a key factor involved in neurogenesis, synaptic integration, and neuronal survival, by evaluating its levels in patients under one year of age with congenital nervous system

anomalies. For this purpose, BDNF levels were analyzed in 90 infants, and patients with central nervous system anomalies (n=70) were compared with a control group (n=20). Mean BDNF levels were 1.47±0.10 ng/mL in patients with CNS anomalies and 7.42±0.10 ng/mL in the healthy group, with the difference being statistically significant ($p<0.001$).

BDNF levels were further analyzed separately according to different CNS anomalies (Table 4). The lowest BDNF levels were observed in cases of meningomyelocele and spina bifida, whereas relatively higher levels were identified in patients with Dandy–Walker malformation.

Table 4

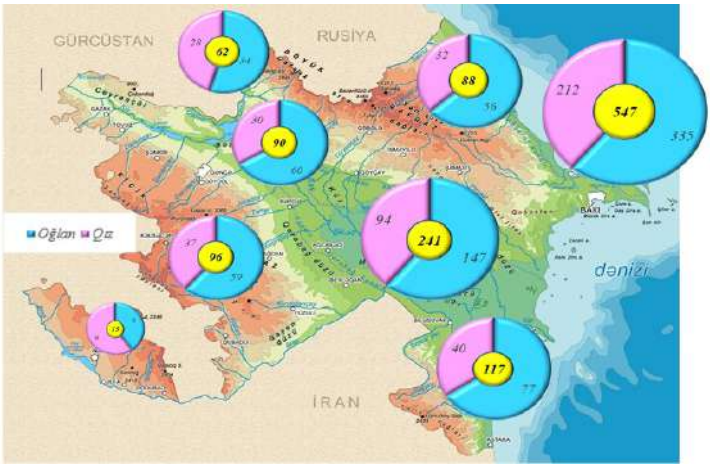
Analysis of BDNF Levels in Congenital Central Nervous System Anomalies

Congenital CNS Anomaly	Number of Patients	Mean BDNF Value (ng/mL)	P_U
Hydrocephalus	46	1.4	< 0.001
Agenesis of the Corpus Callosum	18	1.6	< 0.001
Spina bifida	5	1.4	0.001
Meningomyelocele	5	1.2	0.001
Arnold–Chiari malformation	3	1.7	0.006
Dandy–Walker malformation	2	2.0	0.021
Control group	20	7,3 (7.0-7.9)	

Note: P_U represents the statistical significance of differences in comparison with the control group indicators.

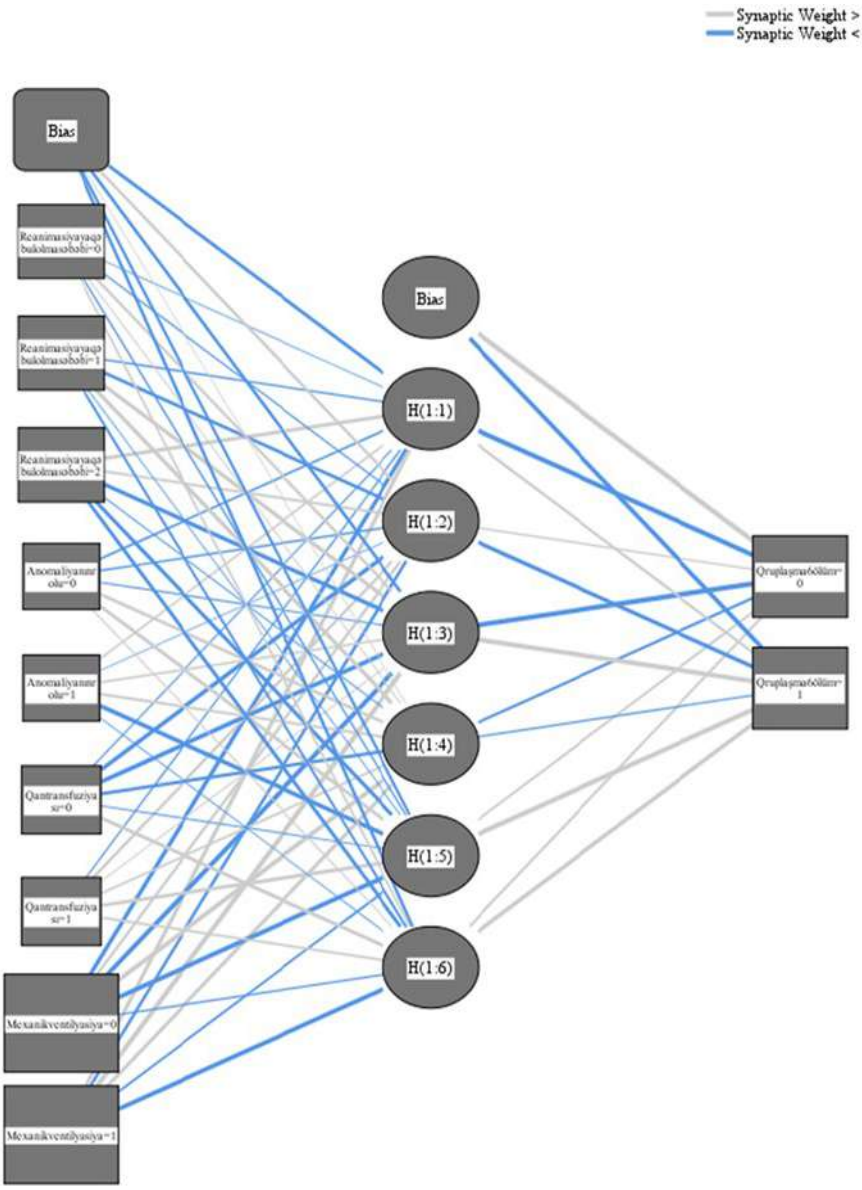
BDNF levels were compared according to survival status in patients with CNS anomalies. Mean BDNF levels were 1.4±0.1 ng/mL in survivors and 1.7±0.2 ng/mL in non-survivors; however, the difference was not statistically significant ($p>0.05$). These findings indicate that although BDNF is informative in identifying the presence of CNS anomalies, it is not a decisive predictor of survival outcome.

Within the framework of the study, a geographical distribution analysis of patients was also performed. The majority of patients under one year of age admitted to the intensive care unit with congenital anomaly diagnoses originated from the Baku and Absheron-Khizi economic region (547 patients). Lower frequencies were observed in other economic regions: a total of 241 patients from the Central Aran, Mil-Mughan, Shirvan-Salyan, and Mountainous Shirvan regions; 117 patients from the Lankaran-Astara region; 90 patients from the Gazakh-Tovuz and Ganja-Dashkasan regions; 96 patients from the Karabakh–Eastern Zangazur region; 62 patients from the Sheki-Zagatala region; and 15 patients from Nakhchivan. Statistical analysis demonstrated no significant differences between the economic regions (χ^2=0.842; p>0.05), indicating a relatively balanced geographical distribution of congenital anomalies (Picture 1).



Picture 1 – Distribution of Patients with Congenital Anomalies Admitted to the Intensive Care Unit According to Economic Regions

In the study, neural network–based prognostic modeling was performed using the clinical and demographic characteristics of critically ill patients under one year of age diagnosed with congenital anomalies. For this purpose, a neural network model was applied, and several variables were incorporated into the analytical model to predict disease outcomes.



Hidden layer activation function: Hyperbolic tangent

Output layer activation function: Softmax

Neural network–based modeling was conducted to predict survival and mortality risk in critically ill patients with congenital anomalies. A total of 1,256 patients were included in the analysis, and the dataset was randomly divided into a training group comprising 871 patients (69.3%) and a testing group comprising 385 patients (30.7%). Clinical parameters incorporated into the model included the reason for intensive care unit admission, the impact of the anomaly on the clinical course, the need for blood transfusion, and the requirement for mechanical ventilation (Figure 7).

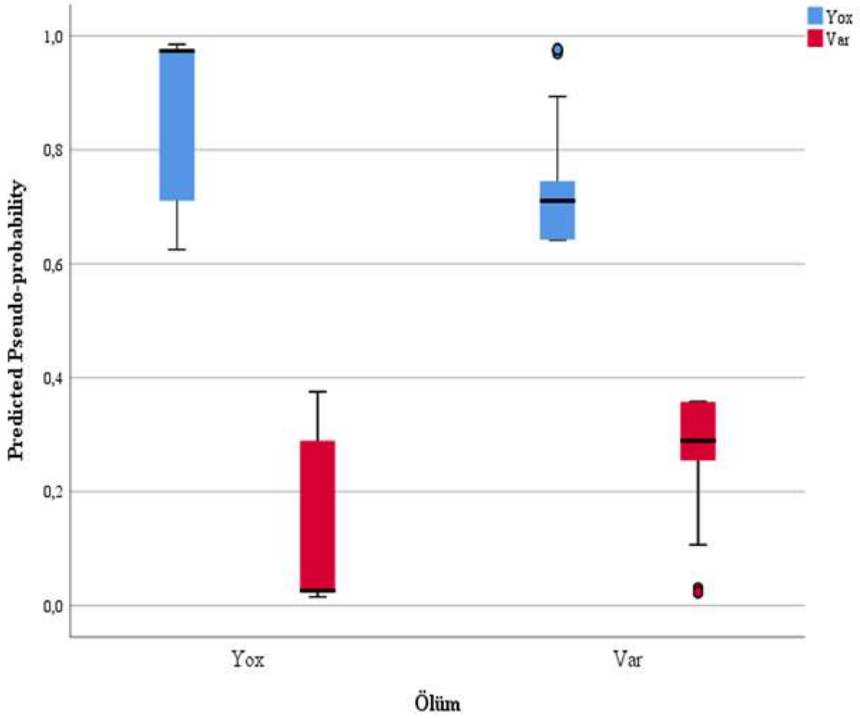


Figure 7 – Distribution of Predicted Pseudo-probabilities for Non-survivors and Survivors Based on the Neural Network Model (Reason for Intensive Care Admission, Impact of the Anomaly on the Clinical Course, Blood Transfusion Requirement, and Need for Mechanical Ventilatory Support)

In the neural network model, mechanical ventilation was identified as the strongest prognostic factor (100%). The prognostic contributions of the remaining variables were considerably lower: reason for intensive care unit admission — 26.9%, blood transfusion requirement — 9.3%, and the prognostic relevance of the anomaly — 2.7%. These findings indicate that the need for mechanical ventilatory support is the principal predictor of mortality risk in critically ill patients with congenital anomalies (Figure 7).

In the study, logistic regression analysis was performed to predict disease severity and survival risk in patients under one year of age with congenital anomalies. A total of 1,249 patients were included in the analysis, while 7 patients were excluded due to insufficient PRISM III data.

Following the initial evaluation of clinical and laboratory parameters, variables with the highest prognostic significance were selected, and the predictive model was subsequently constructed on the basis of these parameters. The inclusion of seven clinical variables significantly improved the discriminatory performance of the model (Table 5).

Table 5.

Forward Stepwise Logistic Regression Analysis

Variable	B	S.E.	Wald	df	Sig.	Exp(B)
Gestational age	-0.615	0.204	9.129	1	0.003	0.540
Mechanical ventilation	2.108	0.280	56.884	1	0.000	8.235
Complications	1.322	0.205	41.552	1	0.000	3.752
Surgical intervention	-0.546	0.215	6.460	1	0.011	0.579
Length of ICU stay (gradual)	-0.461	0.147	9.778	1	0.002	0.631
SNAPPE II score (gradual)	0.884	0.338	6.822	1	0.009	2.420
MINT score (gradual)	1.335	0.218	37.320	1	0.000	3.798
Constant	-4.466	0.604	54.686	1	0.000	0.011

Note: Exp(B) represents the odds ratio.

In the forward (Wald) stepwise logistic regression model, the overall prediction accuracy was 88.9%. Although survival outcomes were predicted with high specificity (97.3%), the sensitivity for predicting mortality was 34.1%.

Patient Condition=–4,466 – 0,615 × gestational age + 2,108 × mechanical ventilation + 1,322 × complication – 0,546 × surgical intervention – 0,461 × length of stay in the intensive care unit + 0,884 × SNAPPE-II grade + 1,335 × MINT grade

Among the variables included in the model, gestational age (24–43 weeks), length of stay in the intensive care unit, and SNAPPE-II and MINT scores were incorporated into the analytical model as quantitative variables, whereas mechanical ventilation, complications, and surgical intervention were included as binary variables. For binary variables, the coding principle of "1" indicating presence and "0" indicating absence was applied.

To facilitate the interpretation of prognostic analysis and simplify practical calculations, several quantitative variables used in the model were categorized. Specifically, SNAPPE-II scores were coded as 1 when <38 points and as 2 when ≥38 points; MINT scores were coded as 1 when <10 points and as 2 when ≥10 points. Gestational age was coded as 1 for <37 weeks and as 2 for ≥37 weeks. Clinical factors, including mechanical ventilation, complications, and surgical intervention, were entered into the model as 1 when present and 0 when absent.

Comparison of the backward and forward logistic regression models demonstrated that both approaches were prognostically effective. In the backward model, the Kappa coefficient was 0.464 ± 0.037 ($p<0.001$), with survival predicted at a specificity of 94% and mortality at a sensitivity of 50.3%. In the forward model, the Kappa coefficient was 0.461 ± 0.037 ($p<0.001$), while survival and mortality were predicted with accuracies of 93.4% and 51.5%, respectively.

The results demonstrated the clinical value of logistic regression models in predicting survival and mortality risk among critically ill children with congenital anomalies, while the reliability of the models was confirmed by the high statistical significance of the Kappa coefficient ($p<0.001$).

The localization of regression indicators in the negative zone among surviving patients and in the positive zone among patients with fatal outcomes confirmed the discriminative ability of the models.

Additional evaluation using a cut-off value of 0.5 demonstrated clinically acceptable sensitivity and specificity.

Furthermore, statistically and clinically significant variables for predicting neonatal mortality risk were identified using forward and backward stepwise logistic regression approaches, as well as a neural network model, thereby improving prognostic accuracy and enabling earlier identification of critical cases.

RESULTS

1. Analysis of data from critically ill patients treated in a level III intensive care unit between 2019 and 2022 demonstrated that congenital anomalies accounted for a substantial proportion of cases in this population (15.2%). The study revealed that the vast majority of identified anomalies were structural in nature (92.3%), whereas only a small proportion were functional or combined structural-functional types. System-based analysis demonstrated that cardiovascular (42.4%) and gastrointestinal (36.2%) anomalies were the most frequently encountered, with statistically significant predominance ($p < 0.05$) [4, 11, 14].

2. The application of the NTISS, SNAPPE-II, CRIB, MINT, and PRISM-III scoring systems in patients under one year of age with congenital anomalies enabled an objective assessment of the severity of critical conditions. In neonates, SNAPPE-II demonstrated prognostic value for predicting the risk of fatal outcomes (AUC = 0.685; $p < 0.001$), whereas MINT showed greater prognostic utility in the assessment of clinical stabilization and the likelihood of transfer/discharge (AUC = 0.743; $p < 0.001$). In patients aged 29 days to 1 year, PRISM-III scores demonstrated a statistically significant association with survival ($p < 0.001$) [10,12,18].

3. In critically ill infants with cardiovascular anomalies, blood NT-proBNP levels were significantly higher compared with the healthy control group (12,811.6 ± 810.7 vs 135.6 ± 14.0 pg/mL; $p < 0.001$), indicating the high diagnostic utility of this biomarker in congenital heart defects. The statistically significant association

between blood lactate levels and survival confirmed its prognostic significance (5.6 ± 0.2 vs 7.9 ± 0.8 mmol/L; $p = 0.017$). A positive correlation identified between NT-proBNP and lactate levels ($\rho = 0.333$; $p < 0.01$) suggested the value of their combined assessment [9,13].

4. In children with gastrointestinal anomalies and anterior abdominal wall defects, I-FABP levels were significantly higher compared with the healthy control group (2.3 ng/mL [2.0–2.5] vs 0.80 ng/mL [0.65–0.88]; $p < 0.001$). The I-FABP biomarker demonstrated high diagnostic utility for predicting the likelihood of surgical intervention (AUC = 0.825; $p = 0.001$), while also showing prognostic significance in the assessment of complication risk and in differentiating between survival and fatal outcomes (AUC = 0.658 and 0.698, respectively; $p < 0.05$) [11,19].

5. In patients under one year of age with nervous system anomalies, BDNF levels were significantly lower compared with the healthy control group (1.47 ± 0.10 vs 7.42 ± 0.10 ng/mL; $p < 0.001$). No statistically significant difference was observed between survivors (1.4 ± 0.1 ng/mL) and patients with fatal outcomes (1.7 ± 0.2 ng/mL) ($P_U = 0.300$) [4,14,19].

6. Prognostic models based on neural network and logistic regression approaches were developed to predict fatal outcomes in critically ill children under one year of age with congenital anomalies. The analysis identified gestational age, mechanical ventilation, presence of complications, length of stay in the intensive care unit, prenatal screening findings, as well as SNAPPE-II and MINT scores, as the principal prognostic factors. The developed prognostic models demonstrated high specificity (97.4%) and overall predictive accuracy (89.0%), indicating their practical value for the early prediction of fatal outcomes in critically ill patients [8,10,12,15].

PRACTICAL RECOMMENDATIONS

1. Timely detection of congenital anomalies during the prenatal period or in the first days after birth contributes to reducing disease-

related complications and fatal outcomes. For this purpose, the systematic implementation of antenatal screening and prenatal diagnostic assessments in pregnant women is considered essential for the early identification of high-risk neonates and the prevention of neonatal complications.

2. The SNAPPE-II and MINT scoring systems are recommended as practical, accessible, and informative tools for assessing the severity of critical illness and prognosis in patients with congenital anomalies, while the PRISM-III scale is considered appropriate for patients aged 29 days to 1 year.

3. Elevated NT-proBNP levels in congenital heart defects, increased I-FABP levels in gastrointestinal anomalies, and decreased BDNF levels in central nervous system anomalies may serve as important biomarkers for the early diagnosis of the respective pathologies, risk stratification, and clinical decision-making.

4. Based on the results of neural network modeling and logistic regression analysis, factors such as duration of mechanical ventilation, gestational age, number of affected organ systems, prenatal screening findings, presence of severe clinical course, duration of intensive care unit stay, and surgical intervention should be considered key prognostic factors in outcome prediction.

5. The prognostic model developed for assessing the severity of critical conditions in children under one year of age with congenital anomalies may be applied in neonatal intensive care units for early risk stratification and the development of individualized treatment strategies.

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The list of Abbreviations

CHD — Congenital Heart Disease
AUC — Area Under the Curve
BDNF — Brain-Derived Neurotrophic Factor
CRIB — Clinical Risk Index for Babies
ELISA — Enzyme-Linked Immunosorbent Assay
EIF — Effect Influence Factor
ICD-10 — International Classification of Diseases, 10th Revision
I-FABP — Intestinal-type Fatty Acid-Binding Protein
MINT — Mortality Index for Neonatal Transportation
CNS — Central Nervous System
NTISS — Neonatal Therapeutic Intervention Scoring System
NT-proBNP — N-terminal pro-B-type Natriuretic Peptide
P_F — Statistical significance level according to Fisher's test
PRISM-III — Pediatric Risk of Mortality III
P_U — Statistical significance level according to the Mann–Whitney test
ROC — Receiver Operating Characteristic
SNAPPE-II — Score for Neonatal Acute Physiology with Perinatal Extension II
SPSS — Statistical Package for the Social Sciences
SRIP — The Scientific Research Institute of Pediatrics named after K.Y. Farajova
WHO — World Health Organization

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