International Journal of Clinical Medicine, 2020, 11, 32-42
https://www.scirp.org/journal/ijcm
ISSN Online: 2158-2882
ISSN Print: 2158-284X

A Prognostic Model of the Development of Postpartum Purulent-Inflammatory Diseases

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How to cite this paper: Bulavenko, O., Ostapiuk, L., Voloshinovskii, A., Rud, V., Malyi, T. and Rud, O. (2020) A Prognostic Model of the Development of Postpartum Purulent-Inflammatory Diseases. *International Journal of Clinical Medicine*, **11**, 32-42.
https://doi.org/10.4236/ijcm.2020.112004

Received: January 23, 2020
Accepted: February 10, 2020
Published: February 13, 2020

Abstract

Background: Currently, postpartum purulent-inflammatory diseases continue to be a prominent issue in medicine. As a result, numerous scientific publications were devoted to finding the solution to this issue. Primarily these solutions included the idea of optimisation of antibiotic-based disease prevention and therapies. However, the early diagnosis and prognosis of these pathologies were unfortunately overlooked. **The Aim of the Study:** To build a prognostic model of the development of postpartum purulent-inflammatory diseases. **Material and Methods:** The main focus of our research was establishment of methods of early diagnosis and prognosis of purulent-inflammatory diseases. The main cohort consisted of 170 women diagnosed with purulent-inflammatory diseases while the control cohort was made of 40 women with an uncomplicated course of pregnancy; patient's blood serum was analysed using fluorescence spectroscopy. Additionally, we implied a variety of standardised algorithms used during clinical and laboratory examination of the patients with postpartum endometritis. **Results:** Fluorescence spectra were studied for 40 women of control group and 170 women of the main group. Based on the data obtained using fluorescence spectroscopy and data from clinical and laboratory examinations (extragenital pathology, gynecology-related diseases, risk of miscarriage, surgery, TORCH-infections, colpitis, labour duration > 12 hrs, labour anomalies, maximum blood serum fluorescence spectrum values, fluorescence spectrum ≤ 0.845, age, number of bed days, fetal distress), we have derived a prognostic model of the development of postpartum purulent-inflammatory diseases. **Conclusion:** As a result, we derived a prognostic model based on the main 13 factors, which contribute to

development of postpartum purulent-inflammatory diseases. This model was determined correct with a probability of over 99% ($p < 0.001$; $\chi^2 = 174.74$; df = 13).

Keywords

Postpartum Purulent-Inflammatory Diseases, Prognostic Model, The Method of Logistic Regression, ROC-Analysis

1. Introduction

Currently, one of the cornerstone issues in modern obstetrics is postpartum purulent-inflammatory diseases (PPPID). Over the past decade, the frequency of PPPID remained between 5% - 20% and despite availability of abundance of medical treatments, it remained one of the core factors behind maternal mortality [1]. Therefore, it will be fair to conclude that this is a crucial issue which has not been resolved as of yet.

Numerous publications were dedicated to this topic, as such they were mostly highlighting optimisation of the existing therapies involving antibiotics. However unfortunately, evaluation of the prognosis and early diagnosis of development of PPPID were severely neglected [2].

A study of individual traits of the patient's organism, in particular, analysis of genetic predisposition to appearance of obstetric and perinatal complications is all a part of predictive medicine. Predictive medicine enables preventative action towards aforementioned complications due to involvement of both prophylactics and determination of aetiological factors and pathogenic mechanisms [3].

High sensitivity and accuracy are the key factors why physical methods of investigation are viewed as highly effective in medical practice. Therefore, the data obtained from clinical and laboratory analysis are core for prognosis of PPPID.

2. Literature Review

It is important to emphasize that the most available diagnostic method for inflammatory diseases is a blood serum test. However, it is also crucial to highlight the findings of other researchers [4] that a diagnostic role and accuracy of leukocyte indicators and leucocytosis itself have not been proved effective in predicting postpartum infections. This finding made us question significance of leucocytosis in administration of antibacterial therapy, because we failed to establish a statistical significance between bacterial infection and leucocytosis overall.

Subsequently, C-reactive protein (CRP) and procalcitonin (PCT) are the most investigated, known and used markers of inflammatory process [5] [6] [7]. CRP is considered a "gold standard" in diagnostics of human inflammatory processes. Moreover, the presence of CRP in blood serum has been implied as an inflam-

matory process marker during pregnancy, preterm premature rupture of membranes and postpartum complications.

An increase in PCT is observed during systemic inflammation during either complex bacterial infections or sepsis. It is important to highlight that PCT reaches its peak values much earlier than CRP. However there is also an opinion that variation in PCT values is not necessarily indicative of an infection or the course of an inflammatory process, especially when there is a presence of haemodynamic instability [7].

Heavy bacterial infections and sepsis contribute to an elevation in PCT concentration in blood serum as a result of extrathyroidal synthesis, taking place in leukocytes, neuroendocrine lung cells and in liver (influenced by pro-inflammatory stimulators). PCT (endotoxins) and pro-inflammatory cytokines IL-6 and TNF are classed as core synthesis inductors. A combination of procalcitonin and the rest of clinical and physical data are considered to be diagnostic markers of sepsis, inflammatory reactions and severity of sepsis among complex patients.

Electron paramagnetic resonance (EPR) analysis of detoxifying efficiency [DTE] of albumin was proposed by another group of researchers as an option for forecasting postpartum endometritis [8] [9].

Logistic regression was implied as a method of statistical processing of the results and data obtained from the experiment. We established the correlation, where DTE ≤ 40% means a high risk of postpartum endometritis, while when DTE ≥ 70% the risk of postpartum endometritis is absent.

A lot of clinical, laboratory and instrumental data is collected during treatment, and there are two core tasks where it is crucially required. First of all, it is development of diagnostics for the disease, especially in preclinical stage. Secondly, prognosis of appearance and development of the aforementioned disease.

During our investigation, along the conventional means of diagnostics, we also implied fluorescent spectroscopy [10] (patent of Ukraine N˚ 33472) as a way to optimize treatment of patients with PPPID. Previously, the aforementioned method was successfully involved in sepsis diagnosis [11] (the patent of Ukraine N˚ 76953) and purulent and sepsis-related complications in gynaecology and obstetrics [2] [12] [13].

Blood serum stimulation was done under wavelength of 280 nm, which corresponds to the range where human albumin is in its' excited state. Although, it is important to point out that there are conformational changes in albumin molecule in blood serum as a result of progression of purulent-inflammatory diseases due to endogenous intoxication; this is related to interaction between albumin molecules and bacterial products of metabolism. During our investigation we were able to determine that a structurally altered albumin would lead to alterations in blood serum fluorescence. Due to the fact that aforementioned method allowed us to determine changes in blood serum within a timespan between 24 - 48 hours prior to any clinical signs, we can confirm that it be suc-

cessfully implied in sepsis diagnosis [2] [11] and monitoring.

We carried out an evaluation of the confirmed risk factors of postpartum endometritis development based on the results from both fluorescent spectroscopy, clinical and laboratory data [14]. Currently, there is a number of approaches used in terms of prognostic models. Logistic regression is considered to be one of the more common approaches [15] [16]. However, these scientists have also argued that there are few complications in implementing it in hospitals due to a lack of training among medical professionals.

Aim: to build a prognostic model of development of postpartum purulent-inflammatory diseases.

3. Data and Methodology

The clinical research centre for this particular investigation was the Department of Gynecology N˚ 2 of Vinnytsia Council Clinical Hospital N˚ 2. The luminescent laboratory of the Department of Experimental Physics, Ivan Franko Lviv National University was an experimental research centre. The research study took place between 2014 and 2018 inclusively.

The main cohort of patients consisted of 170 new mothers with postpartum endometritis. Women with single pregnancy, who had histologically confirmed diagnosis of PPPID in postpartum period were involved in the research. These women were informed beforehand and gave an informed consent for participation in the aforementioned study. Postpartum period after multiple pregnancies, period after antenatal death of the fetus, decompensated somatic illnesses, presence of primary immunodeficiency among postpartum women, presence of HIV infection, tuberculosis (pulmonary and extra-pulmonary), diabetes and a presence of oncological pathology were all considered as exclusion criteria. The control group was made of 40 new mothers with uncomplicated course of the postpartum period. The age of the patients of main cohort and control group was from 18 to 40 years. They were all European and lived in the Vinnytsia region of Ukraine.

Methods of investigation: clinical, laboratory, biochemical, instrumental (uterus and ovarian sonography, bacteriologic and histologic analysis of metroaspirate, fluorescent spectroscopy), mathematical and statistical (logistic regression and ROC-analysis).

3.1. Data Source

As a part of our investigation we thoroughly analysed 40 factors which characterised the unique features of the course of pregnancy, postpartum period and the clinical data obtained from both main and control cohorts of patients. We carried out a detailed analysis of the lab examinations (general blood and urine tests, biochemical blood tests, immunofixation analysis for TORCH-infections, bacterioscopy of vaginal and cervical samples), results of instrumental examination (ultrasonography of lesser pelvis, histological analysis of metroaspirate, fluorescent spectroscopy) and statistical methods (logistic regression and

ROC-analysis).

3.2. Research Results

During this investigation we analysed main indicators of 170 new mothers with PPPID (main cohort) and 40 new mothers with uncomplicated course of postpartum period (control group).

Based on these results we devised a mathematical model used to forecast the risk of development of PPPID. According to the literature sources and our own observations we have picked 17 factors which were at the forefront of the aforementioned diseases and could stipulate a tendency to development of this complication and be potentially related to purulent-inflammatory diseases.

Such factors (Table 1) are as follows: surgery, extragenital and gynecological pathologies, complications during pregnancy and delivery, TORCH-infections, colpitis, fetal distress, invasive procedures during labour, changes in blood serum fluorescence characteristics etc. Quantitative measure of fluorescence intensity has been replaced to a qualitative one. This value will be "1" when patient's fluorescence intensity of blood serum ≤ 0.845, or "0" when fluorescence intensity of blood serum ≥ 0.845.

In terms of cohort formation, women were divided into 4 groups: under 18 years old (Group 0), 18 - 24 years old (Group 1), 25 - 34 years old (Group 2), and older than 35 years old (Group 3).

Table 1. Differences in anamnesis and clinical factors between the control group and main cohort (women with PPPID).

Factor	Control group (n = 40)	Main cohort (women with PPPID) (n = 170)	p
Surgery	12 (30%)	139 (81.8%)	<0.001
Extragenital pathology	7 (17.5%)	102 (60%)	<0.001
Gynecological diseases	12 (30%)	111 (65.3%)	<0.001
Complicated course of pregnancy	19 (47.5%)	143 (84.1%)	<0.001
Invasive procedures during labour	10 (25%)	89 (52.4%)	0.002
Risk of miscarriage	4 (10%)	40 (23.5%)	0.058
TORCH-infections	2 (5%)	74 (43.5%)	<0.001
Colpitis	7 (17.5%)	149 (87.6%)	<0.001
Labour duration > 12 hours	2 (5%)	12 (7.1%)	0.64
Vaginal tears during labour	9 (22.5%)	69 (40.6%)	0.03
Labour anomalies	1 (2.5%)	61 (35.9%)	<0.001
λ_{max} of blood serum	333.63±1.46	335.28±2.29	<0.001
Fluorescence intensity ≤ 0.845 в.о.	6 (15%)	152 (89.4%)	<0.001
Bed days	4.5±1.47	5.69±1.99	<0.001
Fetal distress	1 (2.5%)	36 (21.2%)	0.005
Risk of miscarriage + respiratory disease	2 (5%)	10 (5.9%)	0.82

We performed a stepwise logistic regression (with forward selection) in order to separate the factors, whose cumulative effect would have a significant effect on PPPID.

A probability of PPPID taking place (Q), depending on the selected factors was calculated using the following formula:

$$Q = \frac{1}{1+e^{-R}} * 100\% \quad (1)$$

where $e = 2.72\cdots$—is the base of a natural logarithm,

R—is the quantity calculated according to the Formula (2), mentioned below:

$$R = K + \beta_1 x_1 + \beta_2 x_2 + \cdots + \beta_n x_n \quad (2)$$

where K—a constant,

β_i—coefficients that correspond to a number of calculated factors,

x_i—corresponding numerical values of the factors.

Theoretically, Q can hold a value ranging from 0% (an impossible event) to 100% (a constantly occurring event). The meaning of β_i coefficients is calculated by the software and is represented by the natural log of the correlation of probabilities of corresponding variables. Increasing the value of the independent variable by a unit of measurement would increase the chances of developing complications in EXP (β) times.

The equation was evaluated according to Akaike information criterion [17], verification using χ^2 for the likelihood ratio test and by Nagelkerke's R2 (Pseudo R-squared) [18] [19]. Furthermore, ROC-analysis was used in order to determine a mathematical credibility of the model and calculate an optimal threshold of decision making (cut-off point).

As a result, a ROC-curve was implied in order to demonstrate correlation between specificity and sensitivity. The area under the curve (AUC) was calculated to characterise the model's quality, where the scale varied between 0.5 (method is unacceptable) to 1% - 100% which is an indication of the congruence in prognosis based on the model.

R-studio V1.1.442 was used to carry out statistical analysis, which was then exported for further analysis in MS Excel.

By using logistic regression, we were able to isolate 13 factors out of a total of 17, whose cumulative effect had the biggest impact on development of postpartum endometritis (**Table 2**).

The resulting model is correct with a probability of more than 99% ($p < 0.001$; $\chi^2 = 174.74$; df = 13). We determined that all 13 factors have high impact on development of PPPID, however the extent of this impact varies. EXP (β) is a factor that determines possibility of increased chances of complication arising when the independent variable increases. For instance, an extra bed day during postpartum period increases chances of the patient having postpartum purulent-inflammatory complications by 1.21 times. The biggest influence, however, is showed by a value ≤ 0.845 of fluorescence intensity of blood serum; this value increases chances of complication arising in 604 times. **Table 2** demonstrates results of calculated regression coefficients.

Table 2. The results of regression coefficients related to occurrence of PPPID in the main cohort (n = 170) using logistic regression.

Factor	β	Exp(β)	Variable	z	p
Constant	−78.1471			−0.72	0.472
Surgery	3.8457	46.79	V1	2.72	0.006
Extragenital pathology	2.5346	12.61	V2	1.94	0.053
Gynecological diseases	1.4007	4.06	V3	1.14	0.255
Risk of miscarriage	2.6075	13.57	V4	1.34	0.181
TORCH-infections	2.6978	14.85	V5	1.08	0.282
Colpitis	4.9746	144.69	V6	3.30	0.001
Labour > 12 hours	3.7835	43.97	V7	1.75	0.081
Labour anomalies	0.2017	1.22	V8	0.12	0.902
λ_{max} of blood serum	0.2012	1.22	V9	0.62	0.534
Fluorescence intensity ≤ 0.845	6.4036	603.99	V10	3.39	0.001
Age	0.4201	1.52	V11	0.41	0.685
Bed days	0.1896	1.21	V12	0.57	0.568
Fetal distress	2.7279	15.30	V13	1.08	0.281

By replacing β coefficient with data from **Table 2** in Equation (3) we can determine R and as a result, can forecast the probability of PPPID.

$$R = -78.1471 + 3.8457 * V1 + 2.5346 * V2 + 1.4007 * V3 + 2.6075 * V4 + 2.6978 * V5 + 4.9746 * V6 + 3.7835 * V7 + 0.2017 * V8 + 0.2012 * V9 + 6.4036 * V10 + 0.4201 * V11 + 0.1896 * V12 + 2.7279 * V13 \quad (3)$$

In Equation (3), qualitative factors are demonstrated as a bed day (independent variable V12) and as a max of the blood serum (independent variable V9). Age (independent variable V11) has four levels: 0 – under 18 y.o., 1 – 18 - 24 y.o., 2 – 25 - 34 y.o. and level 3 – over 34 y.o. The rest of the variables are dichotomic, which can be either "1" when the patients have the aforementioned diseases (undergone hospital treatment, TORCH-infections, colpitis or reduction in blood serum fluorescence intensity < 0.845 etc.) or "0" when they are absent.

Nagelkerke coefficient of determination demonstrates which part of dispersion of independent variable can be explained by dependent variable introduced to the model and it equals 0.9076. This therefore confirms that the set of variables explains around 90% of dispersion of dependent variable. The area under the curve (AUC) equals 0.99. ROC-curve, which demonstrates a mathematical model of occurrence of PPPID among the main cohort is depicted on **Figure 1**.

Determination of the optimal threshold of decision making (cut-off point) was done by calculating optimum cut-off value, which maintains equality be-

tween sensitivity and specificity. For this particular model, the threshold was 0.78, leading to a conclusion that a patient is highly likely to be affected if the risk of occurrence of PPPID is >0.78. Threshold of decision making (cut-off point) in relation to specificity, sensitivity and accuracy of the mathematical model for the patients with PPPID in the main cohort is depicted on Figure 2.

At this threshold value of the decision making (cut-off point), sensitivity is 96.47%, specificity is 97.50% (Table 3), likelihood ratio of the positive result (LR+) is 38.58, the likelihood of negative result (LR−) is 0.04, positive prognostic value (PPV) is 99.39% while the negative prognostic value (NPV) is 86.67%.

Table 4 and Table 5 demonstrate selected results of the spectral and fluorescent characteristics of blood serum of both main and control cohorts of patients and corresponding calculation of the probability of development of postpartum purulent-inflammatory diseases. Among the patients in the main cohort (Table 5), only 6 cases had a low likelihood of developing PPPID.

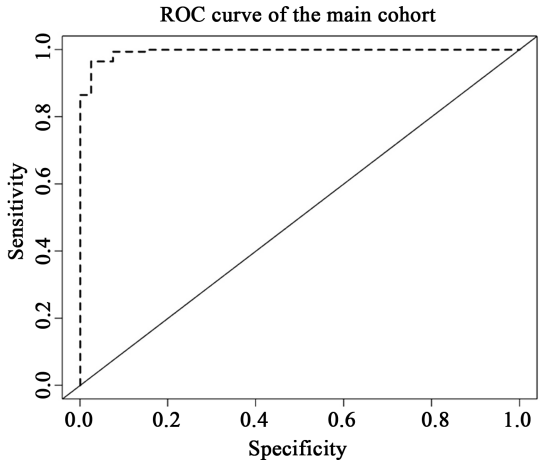

Figure 1. ROC-curve demonstrates a mathematical model of occurrence of PPPID among the main cohort.

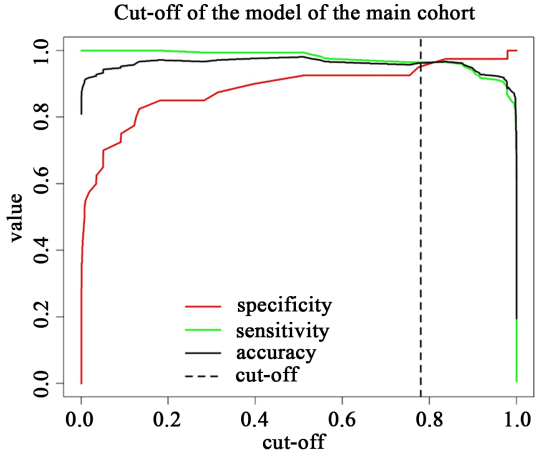

Figure 2. Threshold of decision making (cut-off point) in relation to specificity, sensitivity and accuracy of the mathematical model for the patients with PPPID in the main cohort.

Table 3. Diagnostic value of the mathematical model implied in prognosis of PPPID among new mothers in the main cohort.

	Control group (n = 40)	Main cohort (women with PPPID) (n = 170)	Total
Calculated value < 0.78	39 (97.5%)	6 (3.53%)	45
Calculated value ≥ 0.78	1 (2.5%)	164 (96.47%)	165
Total	40	170	210

Table 4. Probability of PPPID development in control group.

N°	Fluorescence intensity	λ_{max} of blood serum	Probability
1.	0.87	334.6	0.00124
2.	0.89	335.1	0.05022
3.	0.99	332.9	0.00259
4.	0.91	332.6	0.00751
5.	1	331.1	0.09102
6.	0.91	330.1	0.00043
7.	0.87	330.1	0.01822
8.	0.99	333.1	0.00339
9.	0.96	334.5	0.09032
10.	0.95	335.1	0.00056
11.	1	335.1	0.00949
12.	0.97	333.1	0.12568
13.	0.92	333.1	0.00076
14.	0.88	332.1	0.13294
15.	0.83	335.1	0.39702

Table 5. Probability of PPPID development in the main cohort.

N°	Fluorescence intensity	λ_{max} of blood serum	Probability
1.	0.55	334.1	0.99989
2.	0.58	336.1	0.99997
3.	0.61	343.1	0.99999
4.	0.67	336.8	0.91405
5.	0.77	333.3	0.95524
6.	0.63	338.1	0.99999
7.	0.51	337.1	0.99999
8.	0.53	339.1	0.99999
9.	0.57	343	0.99912
10.	1	336.1	0.65298
11.	0.88	333	0.526028
12.	0.89	336.1	0.51114
13.	0.77	332.8	0.55993
14.	0.73	335.1	0.180811
15.	0.71	336	0.54868

4. Conclusions

Within the scope of this investigation we implied fluorescent spectroscopy as the core method in the optimization of diagnostics of patients with postpartum purulent-inflammatory diseases. Based on 13 core factors of prognosis of postpartum purulent-inflammatory diseases (extragenital pathology, gynaecology-related diseases, risk of miscarriage, surgery, TORCH-infections, colpitis, pregnancy duration > 12 hours, anomalies during labour, λ_{max} of blood serum, fluorescence intensity ≤ 0.845, age, bed days, fetal distress) we have built a prognostic model of development of postpartum purulent-inflammatory diseases. Proposed model is correct with a probability of 99% ($p < 0.001$; $\chi^2 = 174.74$; $df = 13$). We determined that all 13 factors can provoke development of postpartum purulent-inflammatory diseases.

To sum up, it was understood that blood serum fluorescence intensity ≤ 0.845 is the largest contributing factor towards postpartum purulent-inflammatory diseases and has the biggest diagnostic value in evaluating the risk of development of these complications (including endometritis) among the main cohort of patients. We determined that according to our prognostic model only 6 patients (3.53%) of the main cohort (Table 3 and Table 5) had no risk of developing purulent-inflammatory diseases post labour.

Conflicts of Interest

Authors declare no conflict of interest regarding the publication of this paper.

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