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# MEDICAL SCIENCES

## PREDICTORS OF ADVERSE COURSE OF SEVERE COMMUNITY- ACQUIRED PNEUMONIA ASSOCIATED WITH CORONAVIRUS INFECTION

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**Introduction.** The global COVID-19 pandemic caused by SARS-CoV-2 has spread from the epidemic centre in Wuhan, China to countries around the world. Unfortunately, the impact of the COVID-19 pneumonia outbreak and the ultimate scope of the pandemic remain unclear. In fact, the fear of COVID-19 has played and continues to play a leading role in the economic and social impact of countries around the world. COVID-19 poses ongoing challenges to the resilience of various socio-economic sectors, including healthcare, travel, the food supply chain, and food businesses (Li Q., 2020; De Vos J., 2020).

In the first published cohort of 41 patients with COVID-19 pneumonia from Wuhan Jinyintan Hospital, six (14.6 per cent) patients deteriorated within a short period of time and died of multiple organ failure. COVID-19 has spread across the globe, and it has wide variations in fatality rates, ranging from 10% in Italy to less than 1% in Germany. Whether or not COVID-19 will be fatal depends heavily on the chances of progression from mild to severe disease and the factors that determine the progression of the disease from pneumonia to severe acute respiratory syndrome, SARS (Severe Acute Respiratory Syndrome) (Huang C., 2020; Hsu C.Y., 2021).

The clinical manifestations of COVID-19 disease are very diverse and range from asymptomatic carriage to symptoms of acute upper respiratory tract infection. Various risk factors that potentially modify susceptibility to infection and disease

severity have been discussed, but it is unclear which factors determine not only the clinical course but also the fate of patients with community-acquired pneumonia (CAP) associated with coronavirus infection. A large retrospective cohort study from Wuhan, China, suggested risk factors such as older age, high SOFA score, and D-dimer levels above 1 µg/ml as markers for predicting poor prognosis. Identification of predictors of adverse outcome in severe coronavirus-associated CAP is clinically relevant as it is crucial for early identification of high-risk individuals, and these patients may benefit from earlier, more aggressive treatment strategies. Also, early and effective predictors of clinical outcomes are urgently needed to stratify COVID-19 risk to help efficiently treat patients and allocate resources (Zhou F., 2020; Balfanz P., 2021; Cellina M., 2022).

**Objective.** To determine predictors of adverse outcome of severe community-acquired pneumonia associated with coronavirus infection.

**Material and methods:** An open, prospective, observational study was conducted to achieve the aim and solve the tasks. In the period from January 2021 to February 2022, patients with community-acquired pneumonia associated with SARS-CoV-2 aged 40 to 65 years were examined at the outpatient clinic of the Kherson City Clinical Hospital named after Athanasius and Olga Tropin of the Kherson City Council, 143 patients were admitted to the hospital. To participate in the study, patients signed the Voluntary Informed Consent to Participate in the Study form.

*Study inclusion criteria:* male and female patients aged 40 to 65 years; community-acquired pneumonia; informed consent to participate in the study.

*Exclusion criteria for the study:* Pregnant women; uncontrolled hypertension; hypertension of the third stage; decompensated diabetes mellitus; congenital and acquired haemodynamically significant heart defects; chronic heart failure of the second and third stages; oncological diseases; lung damage of more than 75% according to CT scan; contraindications to the administration of drugs and their components; alcohol dependence, drug addiction, mental disorders; patient's refusal to participate in the study.

All patients were carefully screened for inclusion/exclusion criteria. The diagnosis of community-acquired pneumonia was verified on the basis of the adapted evidence-based clinical practice guideline Community-Acquired Pneumonia in Adults, 2019. COVID-19 was detected in accordance with Order No. 722 of the Ministry of Health of Ukraine dated 28.03.2020 as amended by Order No. 2122 of the Ministry of Health of Ukraine dated 17.09.2020.

*Distribution of the examined persons into subgroups.* The hospitalised 143 patients with severe CAP associated with COVID-19 were divided into subgroups: those who survived (n = 121) and the second (n = 22) - those who died.

**Medication treatment of patients.** At the stage of inpatient treatment, all patients (n = 143) received oxygen support. Systemic corticosteroids were prescribed: dexamethasone (KRKA, Slovenia) at a dose of 6 mg once daily. Ibuprofen, a non-steroidal anti-inflammatory drug, was prescribed at a dose of 400 mg twice daily (Ibuprofen-Zdorovye, manufactured by Pharmaceutical Company Zdorovye, Ukraine). In the hospital, remdesivir (Corovir, Bruck Pharma PVT, LTD) was also prescribed on the first day in a single dose of 200 mg, and 100 mg per day intravenously on the following days. The treatment course lasted 5 days.

After randomisation, 71 patients were additionally prescribed infusions of standard heparin (Heparin-Pharmex, Farmex Group LLC, Ukraine) at the rate of 1000 IU/h for 10 days, and 72 patients received enoxaparin (Flenox, Farmak JSC, Ukraine) at the rate of 100 IU anti-Xa/kg (1 mg/kg) twice daily for 10 days. The study parameters were assessed on day 3 and 14 after randomisation.

**Statistical processing.** To analyse binary variables, we used the method of logistic regression and ROC analysis (Receiver Operating Characteristic curve analysis), with the calculation of the area under the ROC curve (AUC) and its 95% confidence interval. An AUC value of more than 0.5 was considered statistically significant. To determine the significance of the influence of each of the identified factors, we used the method of building a logistic regression model, which was evaluated using the Wald criterion ( $\chi^2$ ). The OR (odds ratio) of the odds ratio for each of the parameters and the 95% confidence interval were determined.

**Results and discussion.** First, we performed ROC analysis for the values of the dynamics of laboratory parameters (blood glucose, erythrocytes, ESR, haemoglobin, leukocytes, ALT, AST) over 3 days, coagulogram (PT, PI, INR, total fibrinogen, APTT), markers of immune and inflammatory response (hsCRP, IL-6, IL-10, IL-6/IL-10), D-dimer and procalcitonin levels.

We selected 4 indicators ( $\Delta 3$ -day ACP,  $\Delta 3$ -day INR,  $\Delta 3$ -day IL-6,  $\Delta 3$ -day D-dimer), which according to ROC analysis had the largest AUC areas, suggesting that they, regardless of the size of their variance, may be predictors of adverse course of severe CAP. In order to assess the significance of each of the selected factors, the method of univariate logistic regression with Wald's test ( $\chi^2$ ) was applied. When analysing the univariate logistic regression model, it was found that such an indicator as AST was not significant in relation to the unfavourable course of severe CAP. Only such indicators as the dynamic change of  $\Delta 3$  days - INR, IL-6, D-dimer can have a predictable value. Only these indicators were further included in the multivariate logistic regression model. All the analysed dynamic changes in  $\Delta 3$  days of the indexes - INR, IL-6, D-dimer - according to the results of the multivariate logistic regression model were independent predictors of the unfavourable course of severe CAP. According to the results of multivariate logistic regression analysis, the independent predictor of adverse course of severe CAP, D-dimer  $\Delta 3$  days, had an OR = 1.16 with 95 % CI OR 1.06-1.27, IL-6  $\Delta 3$  days had an OR = 1.63, 95 % CI OR 1.21-2.21, while an increase in INR  $\Delta 3$  days by 12.5 % led to a decrease in OR = 0.81, 95 % CI OR 1.21-2.21.

There are limited data in the literature on IL-6, hsCRP, and D-dimer variance in COVID-19-associated CAP. Currently, studies indicate significant laboratory abnormalities in patients with COVID-19 treated in the intensive care unit. In general, our data coincide with the results of these studies. Thus, according to M. Milenkovic et al, elevated levels of IL-6, CRP, PCT, D-dimer and decreased serum albumin levels were found in patients with fatal outcome of the disease. Immuno-inflammatory reactions caused by SARS-CoV-2 are the main cause of disease severity and death. Based on the results of binary logistic regression,

scientists A. Santa Cruz et al. conclude that IL-6 levels were the most significant predictor of non-survivors compared to age and CRP (Milenkovic M., 2022; Santa Cruz A., 2021).

Thus, the data obtained indicate that D-dimer is a reliable predictor of adverse outcome of severe CAP associated with COVID-19. The occurrence of an immunoinflammatory response in patients with severe CAP associated with COVID-19 may play an important role in the course of the disease. Therefore, assessing the dynamics of changes in such a marker as IL-6 is an important additional component of adverse event risk stratification. The use of these laboratory parameters in combination can help identify patients with a lower survival chance. Further, prospective multicentre studies are needed to confirm this.

### **Conclusions.**

1. D-dimer is a reliable predictor of adverse outcome of severe CAP associated with COVID-19.
2. The dynamics of changes in such a marker as IL-6 may be an important additional component of risk stratification for adverse events.
3. The use of D-dimer dynamics in combination with IL-6 may help to identify patients with poorer survival chances.

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