

PCR positivity and D-dimer levels in pregnant women with COVID-19

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Summary

Background: Every day brings us new data on COVID-19, which has come to affect all the dynamics of the society, and increasingly more scientific literature becomes available on the topic. However, research information about its effects on particular groups, e.g., pregnant women, is still very limited. **Aims:** This study was aimed to investigate D-dimer levels in pregnant women admitted to the hospital with suspected COVID-19. **Study Design:** This descriptive cross-sectional study was carried out among pregnant women admitted to our hospital between 1 April 2020 and 31 May 2020 with suspected COVID-19. The data about patients was obtained from patient records and the hospital automation system. **Methods:** The primary outcome variable of the study was the D-dimer levels. Secondary outcome variables were the presence/absence of cough, shortness of breath, headache, fever, weakness, proteinuria, diarrhoea, haematuria, loss of taste, hypertension, and gestational diabetes mellitus. **Results:** Data for 64 pregnant women were analyzed. Thirty-three (51.5%) of them had a positive polymerase chain reaction (PCR) results, and thirty-one (48.5%) had negative ones. The mean age of the participants was 26.33 ± 5.15 years. Of the pregnant women, 51.6% (n = 33) were PCR (+) for COVID-19, and 48.5% (n = 31) were PCR (-). The mean age of the participants was 26.33 ± 5.15 years. Headache occurred significantly more often in PCR (+) pregnant women than in PCR (-) ones ($\chi^2 = 4.201, p = 0.040$). A statistically significant difference was found when the groups were compared in regard to the presence of the fever symptom ($\chi^2 = 5.036, p = 0.025$). When PCR (+) and PCR (-) pregnant women were compared, a statistically significant difference was found in the D-dimer levels ($Z = 2.896, p = 0.004$). A logistic regression model with PCR positivity as the dependent variables and headache, fever, and D-dimer levels as independent ones revealed a Nagelkerke R² of 26.8%, and relatively high sensitivity (87.9%) and specificity (59.1%) values in predicting PCR positivity. **Conclusion:** This research is the first study to have suggested a model for predicting PCR positivity in women suspected of having the COVID-19 disease, which can speed up decision-making in regard to pregnant women with COVID-19.

Key words: COVID-19; Pregnant women; Diagnostic tests.

Introduction

According to the official data, the first positive polymerase chain reaction (PCR) case was registered in Turkey when the World Health Organization (WHO) announced the COVID-19 infection caused by the SARS-CoV-2 virus was spreading from China all over the world as a pandemic [1, 2]. The number of cases increased rapidly going forward, and 178,239 people tested positive for coronavirus in Turkey as of 14 June [2].

Every day brings us new data on COVID-19, which has come to affect all the dynamics of the society, and increasingly more scientific literature becomes available on the topic. However, research information about its effects on particular groups, e.g., pregnant women, is still very limited [3].

Non-specific symptoms such as fever, cough, fatigue, anorexia, weakness, myalgia, sore throat, dyspnoea, nasal congestion, and headache are observed in viral infections of the upper respiratory tract caused by COVID-19. In rare cases, patients may have other complaints, such as diarrhoea, nausea, and vomiting [4]. Also, atypical symptoms may occur, especially in people with weakened im-

munity, elderly people, and pregnant women. Moreover, such COVID-19 infection symptoms as dyspnoea, fatigue, and fever can be confused with the physiological effects of pregnancy [5, 6].

Physiological and mechanical changes in pregnancy increase the susceptibility to the infections in general and speed up progression to respiratory failure in pregnant women, especially if the cardiovascular system is affected [7]. Pregnant women with COVID-19 thus have a risk of developing severe pneumonia. Reportedly, risk profiling, including radiological images and PCR, at the time of admission may improve the chances of risk identification as well as the prognosis in such patients [8].

Objectives

In this study, the symptoms and laboratory results of pregnant women admitted to the hospital with suspected COVID-19 were investigated, and the distinctive features of the PCR-confirmed COVID-19 patients studied. Also, a model was suggested to facilitate the identification of these patients.

Table 1. — Descriptive characteristics of the PCR (+) patients.

Variable		n	%
NSD history	Yes	26	78.8
	No	7	21.2
C/S history	Yes	23	69.7
	No	10	30.3
Cough	Yes	11	33.3
	No	22	66.7
Headache	Yes	23	69.7
	No	10	30.3
Shortness of breath	Yes	30	90.9
	No	3	9.1
Fever	Yes	24	72.7
	No	9	27.3
Weakness	Yes	26	78.8
	No	7	21.2
Proteinuria	Yes	30	90.9
	No	3	9.1
Hematuria	Yes	26	78.8
	No	7	21.2
Gestational DM	Yes	29	87.9
	No	4	12.1

Table 2. — Comparison of numerical variables in PCR (+) and PCR (-) pregnant women.

	Mean		SD		t/Z	p
	PCR (+)	PCR (-)	PCR (+)	PCR (-)		
Age (year)	25.97	26.71	5.25	5.12	0.570	0.570
Gestational Age (weeks)	27.91	27.57	9.55	9.68	0.141	0.889
Hemoglobin (g/dL)	11.97	11.73	1.22	1.50	0.696	0.489
WBC (K/mm ³)	8.033	9.57	3.51	3.22	1.823	0.073
CRP (mg/L)	26.81	28.28	37.0	42.66	*0.74	0.941
Procalcitonin	0.02	0.07	0.03	0.13	*1.370	0.171
Neutrophil (%)	71.84	75.41	6.64	7.95	1.955	0.055
Lymphocyte (%)	18.70	16.14	5.73	7.18	1.578	0.120
D-dimer (mg/L)	1.58	3.27	1.56	3.79	*2.896	0.004
GFR (mL/min/1.73 m ²)	123.31	126.36	17.91	7.41	*0.356	0.722
Urea (mg/dl)	14.91	14.0	5.23	4.15	*0.749	0.454
Creatinine (mg/dL)	0.62	0.58	0.20	0.06	*0.599	0.549
Systolic BP (mmHg)	110.45	112.9	12.77	15.75	*0.174	0.862
Diastolic BP (mmHg)	68.48	70.16	7.95	10.84	*0.417	0.677
Pulse (/min)	94.21	96.23	12.46	11.17	0.679	0.499
SPO2 (%)	97.24	97.61	3.14	0.92	*0.384	0.701

SD: Standard deviation. t: Independent t-test. *: Z: Mann-Whitney U test.

Methods

Study design

This descriptive cross-sectional study was carried out among pregnant women admitted to our hospital between 1 April 2020 and 31 May 2020 with suspected COVID-19. The data about patients was obtained from patient records and the hospital automation system. Ethical approval was received from the Research Council and the Ethical Com-

mittee of the Kharkiv Medical Academy of Postgraduate Education, No16.0220p. The patients gave informed consent to participate. The study report was compiled as per the STROBE guidelines [9].

Participants

During the study period, 5,217 pregnant women applied to the hospital. The symptoms and a history of contact with people having the disease suggested COVID-19

in 64 of them. Therefore, they were hospitalized as suspected COVID-19 cases. The patients were divided into two groups based on PCR results: PCR (+) ($n = 33$) and PCR (-) ($n = 31$) (Figure 1).

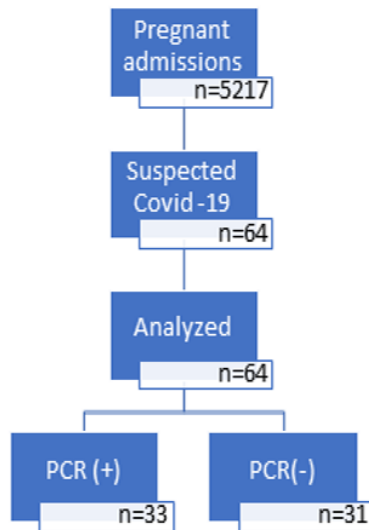


Figure 1. — Participant flow chart.

Variables

The primary outcome variable of the study was the D-dimer levels. Secondary outcome variables were the presence/absence of cough, shortness of breath, headache, fever, weakness, proteinuria, diarrhoea, haematuria, loss of taste, hypertension, and gestational diabetes mellitus (GDM). Besides, the data on the following numerical secondary outcome variables was collected: age (years), pregnancy history (gravidity, parity, normal spontaneous deliveries (NSD), and C-sections (C/S)), body-mass index (kg/m^2) (BMI), gestational age (weeks), haemoglobin levels (g/dL), white blood cell (WBC) count, c-reactive protein (CRP) (mg/L), procalcitonin (ug/L), neutrophil count, lymphocyte count, glomerular filtration range (GFR) ($\text{mL}/\text{min}/1.73 \text{ m}^2$), urea (mg/dL), creatinine (mg/dL), systolic arterial blood pressure (mm Hg), diastolic arterial blood pressure (mm Hg), pulse rate/ min , and, peripheral venous oxygen saturation (SPO2) (%).

Statistical analysis

The Statistical Package for Social Sciences (SPSS) program (SPSS for Windows, Version 25.0, Chicago, IC, USA) was used for statistical analysis. The results were presented as means and standard deviations for numerical variables, and frequencies and percentages for categorical data. The conformity of numerical variables to normal distribution was evaluated with skewness values and histograms.

The numerical variables fitting normal distribution were compared through an independent samples t-test; the analysis of those not conforming to normal distribution was car-

ried out by means of a Mann-Whitney U test; and the Chi-Squared (or Fisher's exact test) test was used for comparing categorical variables. Depending on their distribution, the relations between numerical variables were determined through either Spearman or Pearson correlation analysis. For multivariate examinations, logistic regression analysis with the entered model was used. A p -value of < 0.05 was taken as sufficient for statistical significance.

Results

Of the pregnant women, 51.6% ($n = 33$) were PCR (+) for COVID-19. The mean age of the participants was 26.33 ± 5.15 years. Headache was reported by 30.3% ($n = 10$) of the PCR (+) pregnant patients, while cough was present in 66.7% ($n = 22$) (Table 1).

One of the PCR (+) pregnant women had hypertension (3%), one—loss of taste (3%), and one—diarrhoea (3%). One patient underwent thoracotomy (3%).

When PCR (+) and PCR (-) pregnant women were compared, a statistically significant difference was found in the D-dimer levels. However, other numerical variables showed no discrepancies of note (Table 2).

When the relationships between the variables of pregnant women with PCR positivity were analyzed, significant correlations were found between the D-dimer figure and age, BMI, CRP, as well as procalcitonin levels (Table 3).

Between the PCR (+) and PCR (-) groups ($\chi^2 = 0.505$, $p = 0.477$), the age of those with cough symptoms in PCR (+) patients was significantly higher than those without cough ($t = 2.662$; $p = 0.012$). No such difference was detected in the PCR (-) group ($t = 0.866$; $p = 0.394$).

Headache occurred significantly more often in PCR (+) pregnant women than in PCR (-) ones ($\chi^2 = 4.201$, $p = 0.040$) (Figure 2).

A statistically significant difference was found when the groups were compared in regard to the presence of the fever symptom ($\chi^2 = 5.036$, $p = 0.025$) (Figure 3).

There was no statistically significant difference between the groups as pertains to the presence of weakness ($\chi^2 = 0.271$, $p = 0.603$). Likewise, the groups were compared in regard of proteinuria ($\chi^2 = 0.095$, $p = 0.757$), haematuria ($\chi^2 = 0.035$, $p = 0.851$), diarrhoea ($\chi^2 = 0.419$, $p = 0.607$), required thoracotomy ($\chi^2 = 0.419$, $p = 0.607$), and shortness of breath ($\chi^2 = 0.006$, $p = 0.936$), but no statistically significant difference was detected.

A logistic regression model with PCR positivity as the dependent variables and headache, fever, and D-dimer levels as independent ones revealed a Nagelkerke R^2 of 26.8%, and relatively high sensitivity (87.9%) and specificity (59.1%) values in predicting PCR positivity. However, although the model itself was meaningful, the predictive variables significant in univariate analyses became non-significant in the multivariate regression (Table 4).

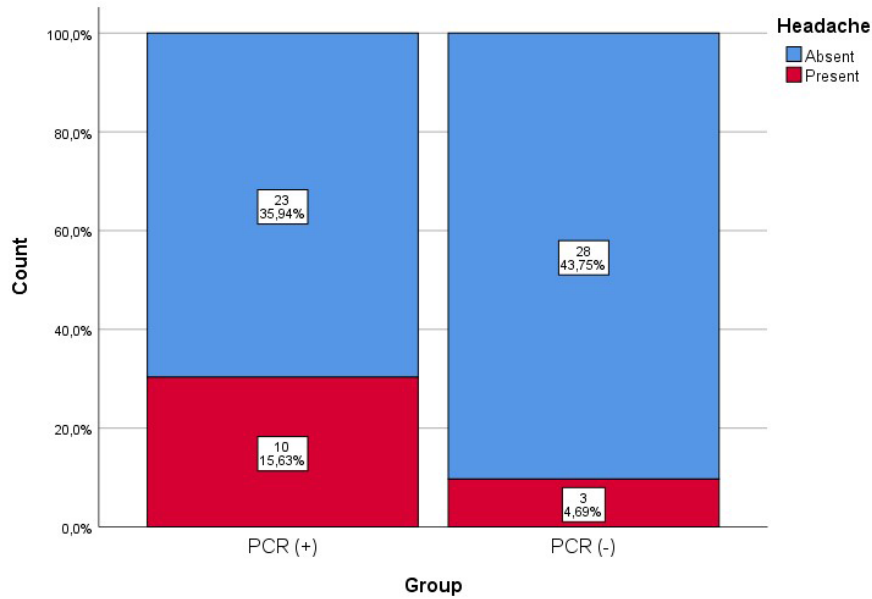


Figure 2. — Group comparison (headache). The distribution of headache between PCR (+) and PCR (-) pregnant women. The red-colored areas show the share of women with headaches. The blue areas show the pregnant ladies without headaches.

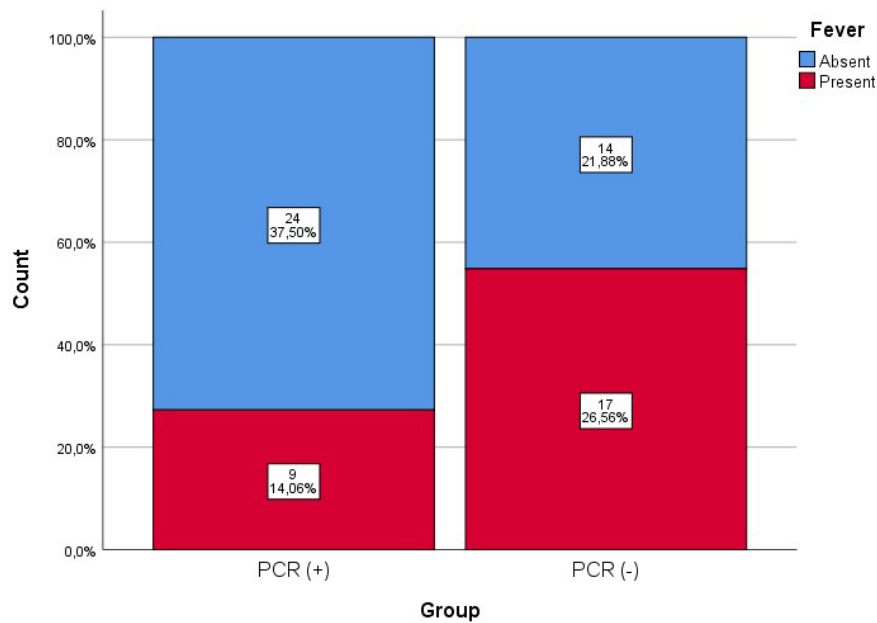


Figure 3. — Group comparison (fever). The distribution of fever between PCR (+) and PCR (-) pregnant women. The red-colored areas show the share of women with fever. The blue areas show the pregnant ladies without fever.

Discussion

Key results

The prevalence of headache was higher in PCR (+) pregnant women than the PCR (-) ones. On the other hand, those with PCR (-) results had higher D-dimer levels and fever.

Limitations

Lack of differential diagnosis of the PCR (-) women and the absence of long follow-up results can be considered lim-

itations of this study.

Interpretation

In December 2019, a new type of coronavirus (SARS-CoV-2) causing severe acute respiratory syndrome was first isolated in the patients diagnosed with pneumonia of unknown origin in China’s Hubei province [10–12]. It was also demonstrated with mathematical models that the infectious property of this new virus is very high [13, 14]. Due to their changing physiology, susceptibility to infections,

Table 3. — Correlation between the numerical variables in PCR (+) patients.

	BMI	GA	HB	WBC	CRP	Proc.	Neu	Lymph	D-dim	GFR	Urea	Crea.	SBP	DBP	Pulse	SPO2
Age	0.488	0.065	0.032	0.102	0.197	0.322	0.135	0.091	0.399	0.664	0.106	0.301	0.328	0.402	0.022	0.296
	0.004	0.718	0.859	0.571	0.271	0.067	0.454	0.616	0.022	< 0.001	0.556	0.088	0.062	0.021	0.905	0.095
BMI	r	0.226	0.426	0.176	0.172	0.223	0.196	0.17	0.453	0.261	0.094	0.262	0.184	0.348	0.038	0.163
	p	0.205	0.013	0.328	0.339	0.211	0.274	0.344	0.008	0.143	0.601	0.14	0.306	0.047	0.835	0.364
Gestational Age	r		0.093	0.066	0.241	0.066	0.043	0.199	0.082	0.359	0.07	0.584	0.234	0.083	0.008	0.005
	p		0.607	0.715	0.176	0.715	0.812	0.268	0.649	0.04	0.697	< 0.001	0.191	0.646	0.964	0.979
Hemoglobin	r			0.089	0.091	0.099	0.133	0.17	0.249	0.025	0.278	0.044	0.242	0.127	0.259	0.017
	p			0.622	0.615	0.583	0.461	0.343	0.163	0.891	0.118	0.807	0.175	0.48	0.146	0.925
WBC	r				0.096	0.088	0.255	0.1	0.149	0.175	0.129	0.187	0.069	0.197	0.173	0.015
	p				0.597	0.627	0.152	0.579	0.409	0.329	0.473	0.297	0.702	0.272	0.337	0.933
CRP	r					0.578	0.46	0.391	0.614	0.084	0.394	0.079	0.417	0.167	0.396	0.55
	p					< 0.001	0.007	0.024	< 0.001	0.641	0.023	0.66	0.016	0.353	0.023	0.001
Procalcitonin	r						0.306	0.272	0.59	0.331	0.078	0.282	0.243	0.083	0.145	0.55
	p						0.083	0.125	< 0.001	0.06	0.665	0.112	0.173	0.646	0.421	0.001
Neutrophil	r							0.907	0.293	0.22	0.152	0.27	0.377	0.28	0.133	0.276
	p							< 0.001	0.098	0.218	0.4	0.129	0.031	0.115	0.461	0.119
Lymphocyte	r								0.158	0.249	0.128	0.408	0.273	0.229	0.054	0.319
	p								0.379	0.162	0.478	0.018	0.125	0.199	0.767	0.07
D-dimer	r									0.239	0.161	0.185	0.345	0.344	0.285	0.453
	p									0.181	0.372	0.303	0.049	0.05	0.108	0.008
GFR	r										0.108	0.73	0.223	0.245	0.056	0.17
	p										0.551	< 0.001	0.211	0.169	0.757	0.345
Urea	r											0.183	0.196	0.286	0.056	0.141
	p											0.307	0.274	0.107	0.757	0.435
Creatinine	r												0.098	0.188	0.086	0.222
	p												0.588	0.294	0.632	0.215
Systolic TA	r													0.476	0.114	0.218
	p													0.005	0.528	0.222
Diastolic TA	r														0.207	0.216
	p														0.247	0.227
Pulsates	r															0.197
	p															0.273

GA: Gestational Age; HB: Haemoglobin; Neu: Neutrophil; Lymph: Lymphocyte; Proc.: Procalcitonin; D-dim: D-dimer; GFR: Glomerular filtration rate; Crea.: Creatinine; SBP: Systolic blood pressure; DBP: Diastolic blood pressure.

Table 4. — Logistic regression model output.

	B	SE	Wald	p	Exp (B)	95% CI for EXP (B)	
						Lower	Upper
Headache (present vs. absent)	1.058	0.87	1.464	0.226	2.881	0.519	15.993
D-dimer	-0.319	0.21	2.362	0.124	0.727	0.484	1.092
Fever (present vs. absent)	-1.036	0.64	2.621	0.105	0.355	0.101	1.244
Constant	1.352	0.61	4.886	0.027	3.864		

SE: Standard Error. CI: Confidence interval.

and mechanical and immunological differences, pregnant women are believed to be a group that should be handled more carefully in such a pandemic [15, 16].

In a review of 108 pregnant women with COVID-19, it was reported that women who presented with fever (68%) and cough (34%) in the third trimester [17]. Reportedly,

70% of those women had high C-reactive protein, 59% had lymphocytopenia, and 91% delivered by C-section. In another study, symptoms including fever, cough, shortness of breath, and anosmia were found to be significantly associated with COVID-19 in pregnancy [18].

Laboratory test results examined in a study comparing

pregnant and non-pregnant women with positive COVID-19 test results demonstrated significantly higher levels of inflammatory markers such as white blood cell count, neutrophil count, C-reactive protein, procalcitonin, and D-dimer. The mean lymphocyte percentage was significantly lower in pregnant women than in the non-pregnant ones [19].

The incidence rates of symptoms in our study were similar to the previous reports. However, it showed for the first time that fever and D-dimer levels were lower in PCR (+) pregnant women compared to PCR (-) pregnant patients. The reason for this finding may be the inclusion of suspected COVID-19 patients. Indeed, fever is a symptom that leads one to suspect a COVID-19 infection. However, it is unclear why D-dimer was lower in PCR (+) pregnant women. Perhaps, it can be attributed to the presence of an undetectable infection with the symptoms similar to COVID-19 in the PCR (-) pregnant women. The situation can be clarified with further studies based on a similar methodology.

Acute renal damage was observed in up to 25% of severe COVID-19 patients [20], similarly to the 33-year-old pregnant woman receiving COVID-19 therapy in Iran [21]. However, no data were obtained during our study to demonstrate any relation to PCR positivity.

The real-time polymerase chain reaction (RT-PCR) method of sampling from the respiratory tract (nasopharyngeal and/or throat swab) is a gold standard for the conclusive diagnosis of COVID-19 infection [7, 22]. However, in the light of such factors as the shortage of personnel, time constraints, and economic reasons, many models have been proposed to predict the diagnosis and severity of COVID-19 infections [23-27]. Unfortunately, these failed to show the desired performance [23]. Furthermore, our research shows there is no such prediction model for pregnant women. In this study, it was claimed that PCR positivity in COVID-19 could be inferred in a specific group of pregnant women based on the symptoms, e.g., headache, fever, and D-dimer, with a relatively high sensitivity but low specificity. This way, potentially harmful imaging methods such as computed tomography can be avoided by relying on simple and accessible data.

Conclusions

This research is the first study to have suggested a model for predicting PCR positivity in women suspected of having the COVID-19 disease, which can speed up decision-making in regard to pregnant women with COVID-19. The fact that it was performed in pregnant women with a relatively high number of COVID-19 positive patients increases the value of the study. However, the findings need to be confirmed by further research.

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Conflict of Interest

The authors have no conflict of interest in this study.

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