



Evaluation of Blood parameters, Covid-19 Vaccine Adverse effects, Hesitancy, and Acceptance rate in Pregnant Women: A Cross-sectional study

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Abstract

The study aimed to analyze pre and post-Covid-19 vaccination adverse reactions experienced by pregnant women. The sum of 145 samples of blood collected from the pregnant women enrolled in Tertiary care hospitals, in Peshawar. Those pregnant women who participated from Peshawar were 54, Dir 23, Charsda 16, Mardan 15, Swat 12, Banu 7, Kohat 4, Malakand 3, Dera Ismail Khan 4, Dara Khyber 2, Mohmand 2, Parachinar 1, Laki marwat 1 and Bajwar was 1. Our study examined the slight change in signs and symptoms in pregnant women against Covid-19 vaccines but did not find any change in the blood parameters. Our findings isolated good results of Covid-19 vaccine acceptance in pregnant women but need more studies and clinical trials to develop a safe, effective and potent vaccine for pregnant women. Recognizing mentalities among study groups will be valuable for coming up with vaccine strategies that increment the ongoing pandemic.

Keywords: Acceptance rate, Covid-19 vaccination, Hesitancy, Pregnant women, signs and Symptoms

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Introduction

The coronavirus is a positive single-stranded RNA virus (+ssRNA) with a crown-like appearance (1-3). Viruses of the family Coronaviridae have been identified in, but not limited to mammals, including mice, dogs, bats, and cats (4). To date, several novel mammalian coronaviruses such as SARS (severe acute respiratory syndrome) and MERS (Middle East Respiratory Syndrome) are pathogenic to humans (5).

After a few days, the start of symptoms is seen with the highest viral loads in the upper respiratory tract. In the absence of containment measures, symptomatic patients represent the largest transmission potential with a risk of spreading the infection via coughing and sneezing to increase the number of droplets that are ejected in the air or on surfaces (6).

Challenges being faced to implement different programs against the Covid-19 vaccine includes



the synthesis of vaccines, their distribution, and ambiguity in the long-term efficacy of the use of vaccines(7). But it has been found that the major factor that was responsible for the hurdles in controlling and reducing the negative consequences of the Covid-19 pandemic is vaccine hesitancy(8). Spreading awareness through different channels and programs, and making the public aware of the efficacy of the vaccines can help build trust in Covid-19 vaccination(9).

Pregnant women with the Covid-19 vaccine may be at expanded risk for unfavourable pregnancy results, and preterm birth, as compared to pregnant women without the Covid-19 vaccination(10, 11). The CDC (Centers for Disease Control and Prevention) in a joint effort with the "American College of Obstetricians and Gynecologists" and "the American Academy of Pediatrics" have given direction demonstrating that Covid-19 immunizations ought not to be kept from pregnant women (12, 13).

The study aimed to analyze the signs and symptoms experienced by pregnant women pre covid-19 vaccination and post Covid-19 vaccination. To screen the effect of Covid-19 vaccines on blood parameters in pregnant women.

Methodology

The study was designed at the Molecular Virology Laboratory, Department of Microbiology, and The University of Haripur. The study was conducted at the Department of Pathology, Tertiary care Hospital Peshawar.

was 2, Parachinar was 1, Laki marwat was 1 and Bajwar was recorded for 1.

Consents in study

We developed a questionnaire by using Microsoft word version 2016 for each study candidate. It contained a few questions such as ethical approval, study participation and medical history. They were released sign at the bottom of the consent form.

Haematological Analysis

We used a Rayto-7600 analyzer for the analysis of the blood parameters such as complete blood test. Rayto-7600 can calculate the 23 blood parameters, and display 3 histograms, with two counting channels. It uses whole blood specimens and can store results for long memory. All the results displaying on the colourful LED(14).

Biochemical Analysis

We used Microscan-400 for the analysis of Biochemical parameters such as Liver Function Tests (LFTs) Renal Function Tests (RFTs) and Serum Electrolytes. Microscan-400 is fully automated, has good accuracy in test results, and is easy to use.

Biochemical reagents

We used Martin Dow Marker reagents due to the high sensitivity and specificity rate of the reagents. We also used Martin Dow Marker Calibrators and controls in the study.

Results

Study design

The sum of 145 samples of blood collected from the pregnant patients enrolled in Tertiary care hospitals, in Peshawar. They were classified based on the residency or district as Peshawar was recorded for pregnant women as 54, Dir was 23, Charsda 16, Mardan was 15, Swat was 12, Banu was 7, Kohat was 4, Malakand was 3, Dera Ismail Khan was 4, Dara Khyber was 2, Mohmand



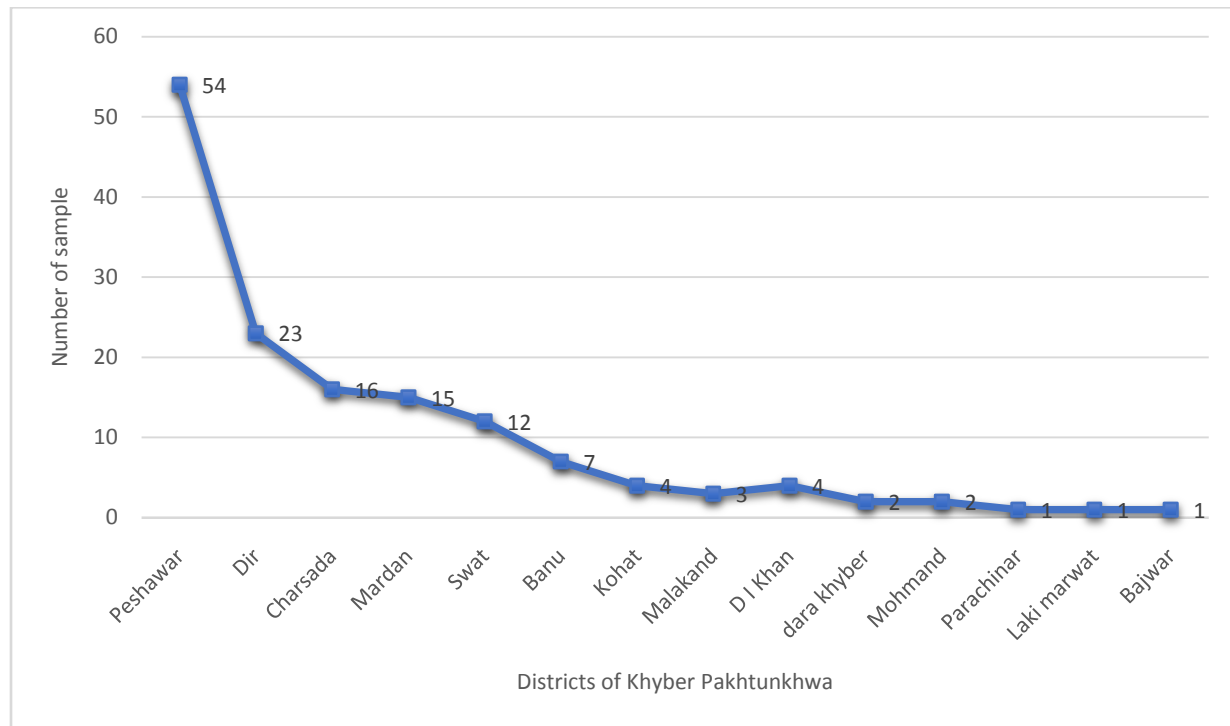


Figure no.1 the participation of pregnant women based in a residential area

Pre and Post-vaccination in pregnant women

Table No.1 Pre and Post Covid-19 vaccination analysis of Signs& symptoms in pregnant women

Sign and Symptoms		Mean	Std. Devotion	Sig value p= <0.05
Fever	Pre and Post	-660	± .557	.000
Cough	Pre and Post	-.083	± .302	.001*
Loss of test/smell	Pre and Post	-347	± .662	.000
Sore throat	Pre and Post	-181	± .58 7	.000
Headache	Pre and Post	-.382	± .488	.000
Aches and pain	Pre and Post	-.139	± .347	.000
Diarrhea	Pre and Post	.007	± .083	.319



Shortness of breath Pre and Post -0.292 ± .456 .000

***Significant at p <0.005**

Figure No.1 Data analysis of pre and post-vaccination signs and symptoms

Paired Samples Test

	Paired Differences	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
					Lower	Upper			
Pair 1	Fever bef- Fever after	-.660	.557	.046	-.751	-.568	-14.219	143	.000
Pair 2	Cough bef- cough after	.083	.302	.025	.034	.133	3.317	143	.001
Pair 3	Loss test/smell bef- Loss test/smell after	-.347	.662	.055	-.456	-.238	-6.296	143	.000
Pair 4	Sore throat BEF- sore throat after	-.181	.587	.049	-.277	-.084	-3.690	143	.000
Pair 5	Headache bef- Headache aft	.382	.488	.041	.302	.462	9.401	143	.000
Pair 6	Aches and pain bef- Aches and pain aft	.139	.347	.029	.082	.196	4.803	143	.000
Pair 7	Diarrhea bef- Diarrhea	-.007	.083	.007	-.021	.007	-1.000	143	.319
Pair 8	shortness of breath bef- shortness of breath aft	.292	.456	.038	.217	.367	7.673	143	.000

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Table No.2. Pre and Post Covid-19 vaccination analysis of blood parameters in pregnant women

Paired Differences		95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)	
Mean	Std. Deviation	Lower	Upper			Sig value p= <0.05	
Pre-WBC s and Post WBCs		-.5317	3.5355	-1.1121	.0486	-1.811	145 .072
Pre-Neutrophil and Post-Neutrophil		14.345	86.051	.220	28.470	2.007	145 .047*
Pre-Lymphocytes and Post-Lymphocytes		-13.889	81.888	-27.378	-.400	-2.035	145 .044*
Pre-Eosinophil and Post-Eosinophil		-.055	1.517	-.304	.194	-.438	145 .662
Pre-Platelets and Post Platelets		3.979	112.287	-14.517	22.476	.425	145 .671
Pre-Urea and Post-Urea		.041	9.130	-1.457	1.540	.055	145 .957
Pre-Creatinine and Post-Creatinine		.014	1.637	-.255	.283	.101	145 .919
Pre-ALT and Post-ALT		.221	9.442	-1.329	1.771	.281	145 .779
Pre-ALP and Post-ALP		-.069	24.507	-4.092	3.954	-.034	145 .973
Pre- Na+ and Post-Na+		.138	4.684	-.631	.907	.355	145 .723
Pre-K+ and Post-K+		-.007	.741	-.128	.115	-.112	145 .911
Pre-Cl and Post-Cl		-.041	3.793	-.664	.581	-.131	145 .896

*Significant at p <0.005, t-t-value, df-difference

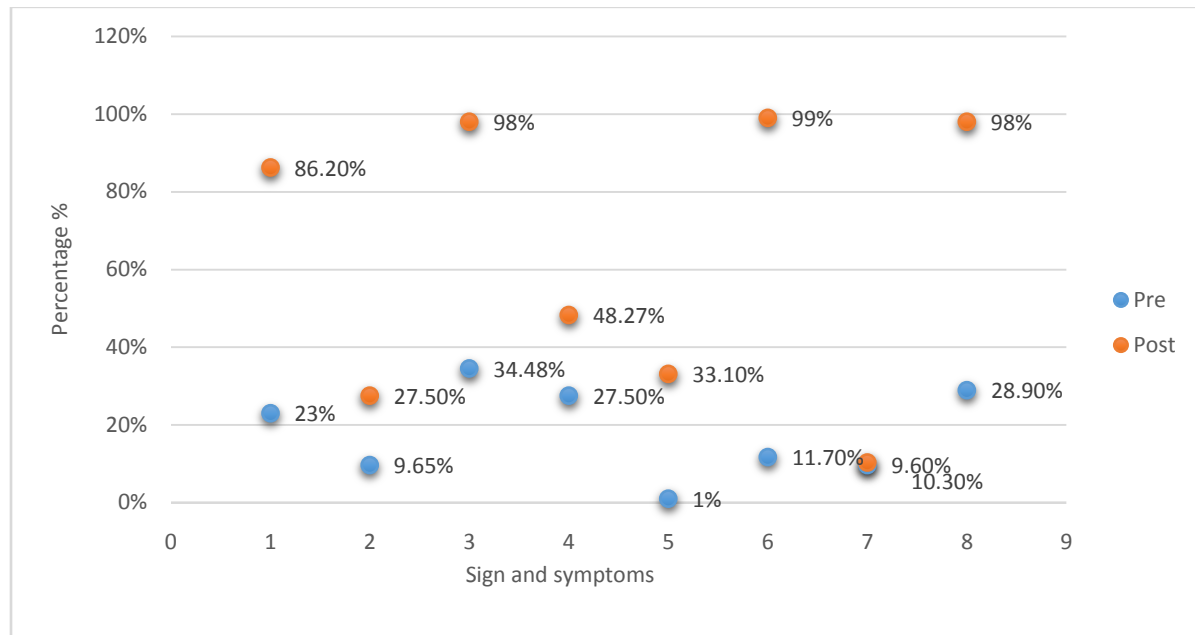
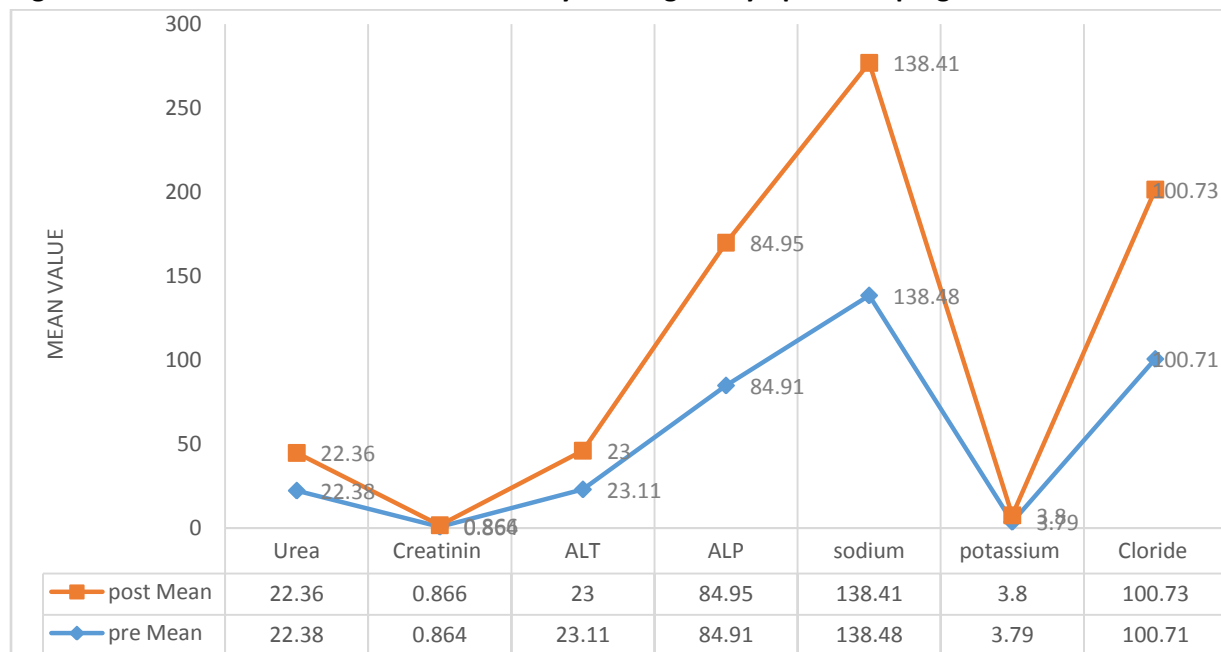


Figure No. 2 Distribution of Pre and Post analysis of Signs& symptoms in pregnant women



**Figure No.3The mean of Pre and Post-vaccination of Biochemical parameters in pregnant women
 The hesitation about Covid-19 vaccines**

Table no.3 Questions answered by pregnant women for the hesitation of Covid-19 vaccines

Hesitancy Reason	(n=145) %	CI	P-value
Not Believe in Covid-19	20.5		



A vaccine is safe?	72		
Do not Know about vaccine	8		
A vaccine is a good option	42	95%,1.960	0.001*
Pregnancy	64		
Comorbidities	5		
On other vaccines	1.5		

CI=confident interval, *significant at <0.05

The hesitation of Covid-19 vaccines in pregnant female

Table no.4 Hesitancy of Covid-19 vaccines in pregnant females

Pregnancy Chart	n=145	8 weeks	10 weeks	12 weeks	15 weeks	22 weeks	28 weeks
1 st Trimester	31	9	4	18	0	0	0
2 nd Trimester	68	0	0	0	51	17	0
3 rd Trimester	46	0	0	0	0	0	46

Table no.5 Comparative analysis of Trimester & weeks by One-Way ANOVA

Variables	SS	df	MS	F-value	P-value
Between Trimester & weeks	115.4444	2	57.7222		
Within Trimester & weeks	4143.5	15	276.2333	F = 0.20896	0.8137
Total	4258.9444	17			

SS (sum of squares deviation of data), df (Difference), MS (the mean sum of squares of data), and F (the F-statistic).

Post Hoc Tukey Test

Table no.6 Pairwise difference, comparison and hesitancy of Covid-19 vaccines on 1st, the 2nd and 3rd Trimester by Post Hoc Tukey HSD

Pairwise Comparison	HSD	Q	P=	Alpha (Top)	Alpha (Bottom)
1 st Trimester=5.17 2 nd Trimester=11.33	6.17	0.91	0.799	.05 = 3.7729	Q.01 = 5.0459
1 st Trimester=5.17 3 rd Trimester=7.67	2.5	0.37	0.963		
2 nd Trimester=11.33 3 rd Trimester=7.67	3.67	0.54	0.923		

The standardized range statistic (q), the critical values for q corresponding to alpha = .05 (top) and alpha = .01 (bottom).



Discussion

Rasmussen et al. suggested that pregnant women were added to clinical trials in small numbers (15). Bianchi et al., released guidelines in June 2020, in which FDA recommended that before the enrollment of pregnant women in the trials, the pharmaceutical companies should conduct different toxicological studies regarding their reproductive strategies, in the women whose pregnancies are not being avoided in the trials (16).

The results were submitted by Wainstock et al., to FDA on 4th December 2020, demanding the enrollment of pregnant women. It has been reported that the toxicological studies on reproductive and developmental concerns, on Pfizer-BioNTech, are most probably to be sent in the upcoming time FDA (17). As predicted by Falsaperla et al., the documentation of the Moderna vaccine has reported the trials on postnatal and perinatal stages of rats. which showed that there were no harmful effects on the fetus of the rat in the developmental stages (18). Van Spall, described that many companies developing Covid-19 vaccines are planning to include pregnant women in the trials in the upcoming years, still in the current studies they were being excluded and it was being requested to stop their pregnancy for months after injection. So less data is available on the efficacy of these vaccines in pregnant women (19). Pilishvili et al., reported in November by Pfizer that almost 23 pregnant persons were included in the trials, among which 12 were present in the vaccine group and continuing their pregnancies. While in the report being passed by Moderna, it was found that there were 13 pregnancies in the trials, among which seven were present in the placebo group while six were in the vaccine

group (20). It has been reported by Moro et al., to the CDC that, almost 300,000 the 75% of healthcare women, can be pregnant or postpartum at the time when the vaccine was being implemented (21).

Einav et al. reported that during pregnancy, vaccines were allowed in the case when it was recommended that there was a less harmful effect of the vaccine than the benefit (22). Marbán-Castro et al. elaborated that different clinical trials against Covid-19 vaccines have been done in pregnant women but there are no successful attempts to be done against mRNA vaccines, which were the first vaccines to be available for treatment (23). Yong et al. found that the Pfizer-BioNTech vaccine has the potency to show reactions in the form of chills, headaches, joints, and muscle pain. 37% of patients were found to have a fever after having 1st dose of Pfizer-BioNTech while 15.8% experienced fever after 2nd dose, having the age of 18-55 years. The babies born to women who were having fevers during the first trimester were known to have certain critical birth defects (24). Farrell et al. recommended by Women's health authorities those women who were going through the phase of pregnancy should discuss the risk of vaccinations with their healthcare providers (25).

Conclusion

Our study analyzed the slight change in signs and symptoms in pregnant women who were administered the Covid-19 vaccines whereas no change was observed in the blood parameters. Our findings concluded good results of Covid-19 vaccines in pregnant women but need more studies and clinical trials to develop a safe, effective and potent vaccine for pregnant women.



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