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Original Research Article.

A Prospective Hospital Based Study to Correlate the Coagulation Profile in All Three Trimesters of Pregnancy

Dinesh Parmar[1], Shalu Parihar[1*]

[1]**Associate Professor, Department of General Medicine, Government Medical College, Barmer, Rajasthan, India.**

ABSTRACT

Background: The basic changes in hematological parameter in pregnant ladies in all the trimesters so we can label it as normal routine physiological changes. As Indian data in this context are lacking so this study was planned to assess incidence of coagulation abnormalities in pregnancy and to correlate these coagulation abnormalities with risk factors (body mass index, blood pressure and glycemic status).

Materials & Methods: This is a observational prospective analytic study done on 50 eligible pregnant ladies who full filled the inclusion and exclusion criteria were enrolled in the study. After taking proper history, all the subjects underwent clinical examination comprising of general physical examination, assessment of vital parameters and systemic examination. FDP and D-dimer done by FINECARE instrument with latex agglutination method. Continuous variables were summarized as mean and standard deviation and were analyzed using repeated measure ANOVA test for intra group comparison at different trimester and one way ANOVA test for inter group comparison.

Results: The results of this study showed that coagulation trends in all three trimesters of pregnancy and also correlate them with blood pressure status (normotensive, chronic hypertensive and pregnancy induced hypertension) and blood sugar status. FDP, D-Dimer, APLA and INR are increased while platelets counts, PT and aPPT was declined.

Conclusion: We concluded that there was a increased in FDP, D-Dimer, INR, APLA while platelets count, PT and aPTT were decreased. This study constituted a platform for such larger studies.

Keywords: Coagulation Profile, Pregnancy, D-dimer, FDP, INR, PT, aPTT.

***Correspondence to:**

Dr. Shalu Parihar,
Associate Professor,
Department of General Medicine,
Government Medical College, Barmer, Rajasthan, India.

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INTRODUCTION

Pregnancy is associated with various physiological changes, which tend to affect most of the body system and some of these begin immediately after conception continuing through delivery to the postpartum period in order to accommodate both the maternal and fetal needs. During pregnancy is a characterized physiological change in the activating and inhibitory pathways of coagulation and fibrinolysis result in an accelerated, but well balanced, process of thrombin formation and resolution. These changes serve to protect the mother from the hazard of bleeding imposed by placentation and delivery, but they also carry the risk of an exaggerated response, localized or generalized, to coagulant stimuli.[1]

There are so many factors which directly or indirectly affects the coagulation system just like co-morbid condition (hypertension, diabetes mellitus, thyroid disorders), Infections, Disseminated Intravascular Coagulation (DIC), obesity, dietary habits etc. which produces morbidity and mortality in antepartum as well as postpartum periods.

Pregnancy induced hypertension (PIH) is defined as hypertension that develops as the direct result of gravid state. It includes gestational hypertension, Preeclampsia and Eclampsia. Chaware SA et al (2017)[2] studied and found that severe Preeclampsia and eclampsia were characterized by thrombocytopenia and coagulation abnormalities indicating intravascular coagulation. Platelet count and aPTT had predictive value in screening for consumptive coagulopathy in the severe cases of Preeclampsia and eclampsia.

Sharma UK et al (2016)[3] conducted a study and concluded that the abnormalities pertaining to coagulation parameters in PIH indicate the impending intravascular coagulation.

Obesity is characterized by disturbances in blood coagulation including enhanced platelets activation, increased concentration and enhanced activities of plasma coagulation factors as well as impaired fibrinolysis in form of increased production of plasminogen activator inhibitor (PAI-1). Several other mechanisms, such as systemic inflammation, endothelial

dysfunction, disturbance of lipid and glucose metabolism and insulin resistance also contribute to the hypercoagulable state in obesity. Adiposity may functionally alter the function of several genes in the coagulation cascade.

Pregnant women in which higher level of D-dimer and aPTT was found, they have higher incidence to develop severe preeclampsia and need aggressive treatment. Nirmala et al[4] also showed that D-Dimer and aPPT were closely related to preclampsia. Swarropa et al[5] studies on effectiveness of D-dimer in venous thromboembolism and found that d-dimer level was higher in VTE.

According to World Health Organization, one woman dies every minute from a pregnancy-related complication. The antepartum and postpartum hemorrhage remains one of the main causes of mortality.[6] Thus, it is important to know variations in hemostatic profiles during pregnancy so that adequate measures can be taken well in time to minimize pregnancy related morbidity and mortality.

As Indian data in this context are lacking so this study was planned to assess incidence of coagulation abnormalities in pregnancy and to correlate these coagulation abnormalities with risk factors (body mass index, blood pressure and glycemic status).

MATERIALS & METHODS

This is a observational prospective analytic study done on 50 eligible pregnant ladies who full filled the inclusion and exclusion criteria were enrolled in the study.

Inclusion Criteria

- Pregnant women willing to give consent to participate in the study.

Exclusion Criteria

- Previous Thromboembolic episode
- H/o Oral contraceptive pill
- H/O Acquired Thrombophilia or Family History
- H/O Previous Complicated Pregnancy
- H/O Smoking
- H/O Malignancy

Methodology

Pregnant ladies who were visited to routine antenatal clinic in the department of Obstetrics & Gynecological & department of Medicine, Government Medical College and attached group of hospitals in Barmer, Rajasthan, Baseline clinical characteristics including demographic, clinical and biochemical data were collected.

Clinical Examination

After taking proper history, all the subjects underwent clinical examination comprising of general physical examination, assessment of vital parameters and systemic examination.

Blood Pressure Measurement

Blood pressure was measured in the arm manually by following the guidelines given by the British and Irish Hypertension Society 2017[7] Blood pressure was measured twice for each subject.

Laboratory Investigations

All eligible pregnant women were asked to come after eight to ten hours of overnight fasting. Taking universal precaution measures and following the aseptic technique, blood samples were withdrawn from each study subject. These samples were placed into appropriate vials for transport to laboratory for the following investigations.

- Complete blood count, differential leucocytes count, ESR
- Fasting Blood Sugar, Random Blood Sugar, HbA1c
- Liver function test (Serum Total Protein, Albumin, A: G Ratio, SGOT, SGPT, ALP, total bilirubin d/l)
- Renal function test (S. urea, S. creatinine)
- Lipid profile (total cholesterol, total lipid, triglyceride, LDL, HDL)
- Thyroid Function Test (FT3, FT4, TSH)
- Coagulation profile (FDP, D-Dimer, PT-INR, aPTT, APLA)

Specimen Collection and Hematological Analysis

Blood sample were collected from 50 pregnant women in all three trimesters. About 6 ml venous blood samples were drawn by the lab technician from pregnant women. Each blood sample was divided into EDTA tube (2ml), 3.2% Tri-Sodium Citrate tube (2ml) and plain tube (2ml). EDTA tube was used for complete blood count, then added blood sample to citrated tube for ESR analysis. Tri sodium citrate tube was used for PT, INR, APTT and fibrinogen analysis. Plasma samples were obtained by centrifugation at room temperature at 4000 rpm for 10 minutes to analyzed samples during 3 hours after blood collection. Plain tubes were left for short time to allow blood to clot. Then, serum samples were obtained by centrifugation at room temperature at 4000rpm for 5 minutes to measure serum related investigations.

Determination of FDP & D-Dimer

FDP and D-dimer done by FINECARE instrument with latex agglutination method.

Reference value:

FDP - <5 ug/ml

D-Dimer-(ug/ml)

Non-Pregnant	<0.5
1 st trimester	0.05-0.95
2nd trimester	0.32-1.29
3rd trimester	0.13-1.7

Determination of PT and INR

BioMed- Liquiplastin for PT determination with using Biomed Diagnostics reagent by electrochemical clot detection with plasma (citrated).

Reference value: PT - 11.0 - 14.0 sec and mean normal INR 0.8-1.10

Determination of Activated Partial Thromboplastin Time (APTT):

For quantitative determination of APTT done with electrochemical clot detection with plasma by SAGO SATRT instrument.

Reference value: 30- 40 sec

Statistical Analysis

Nominal / categorical variables were summarized as frequency and percentage. Continuous variables were summarized as mean and standard deviation and were analyzed using repeated measure ANOVA test for intra group comparison at different trimester and one-way ANOVA test for inter group comparison.

RESULTS

The present study showed that the mean age of study subjects was 26.47 ± 3.35 years with most of the subjects (50) being in the age of 25 – 29 years. Most of the ladies belongs to rural areas (64%), Hindu religion (74%) and housewife (86%) by occupation. (Table 1)

Table 1: Demographic profile of study subjects

Demographic profile	N (50)	Percentage
Age group (years)		
20-24	14	28
25-29	25	50
30-34	11	22
Religion		
Hindus	37	74%
Muslim	13	26%
Residence		
Rural	32	64%
Urban	18	36%
Gravida		
Multigravida	20	40%
Primigravida	30	60%

Table 2: Association of D dimer (µg/ml) level with BMI, Glycemic status & blood pressure status

Trimester	D dimer (µg/ml) level			P value
	First	Second	Third	
BMI (kg/m²) (Mean ± SD)				
<18.5 (n=2)	0.81 ± 0.56	1.18 ± 0.57	1.53 ± 0.60	0.067(NS)
18.5-24.9 (n=38)	1.17 ± 0.57	1.52 ± 0.58	1.93 ± 0.67	<0.001(S)
≥24.9 (n=10)	1.28 ± 0.46	1.68 ± 0.41	2.07 ± 0.52	<0.001(S)
P value	0.129(NS)	0.113(NS)	0.144(NS)	
Glycemic status (blood sugar level) (Mean ± SD)				
<126mg/dl	1.11 ± 0.50	1.46 ± 0.51	1.82 ± 0.59	<0.001(S)
≥126mg/dl	1.41 ± 0.70	1.80 ± 0.67	2.37 ± 0.73	<0.001(S)
p-value	0.023(S)	0.012(S)	<0.001(S)	
Blood pressure status				
Normotensive	1.10 ± 0.51	1.46 ± 0.51	1.86 ± 0.58	<0.001(S)
Chronic HT	1.51 ± 0.80	1.75 ± 0.81	2.17 ± 0.94	0.315(NS)
PIH	1.44 ± 0.59	1.91 ± 0.65	2.34 ± 0.85	0.043(S)
P value	0.042(S)	0.039(S)	0.060(NS)	

Table 3: Association of FDP (µg/ml) level with BMI, Glycemic status & blood pressure status

Trimester	FDP (µg/ml) level			P value
	First	Second	Third	
BMI (kg/m²) (Mean ± SD)				
<18.5 (n=2)	11.00 ± 4.72	17.87 ± 8.44	24.87 ± 9.17	0.006(S)
18.5-24.9 (n=38)	12.34 ± 4.07	19.63 ± 5.78	26.09 ± 7.86	<0.001(S)
≥24.9 (n=10)	16.40 ± 8.86	23.55 ± 9.00	30.32 ± 9.80	<0.001(S)
P value	0.008(S)	0.046(S)	0.112(NS)	
Glycemic status (blood sugar level) (Mean ± SD)				
<126mg/dl	13.20 ± 5.82	20.10± 7.32	25.66 ± 8.50	<0.001(S)
≥126mg/dl	12.47 ± 4.83	21.96 ± 5.06	31.29 ± 6.93	<0.001(S)
p-value	0.601(NS)	0.617(NS)	0.006(S)	
Blood pressure status				
Normotensive	13.06 ± 5.59	20.38 ± 7.12	26.89 ± 8.88	<0.001(S)
Chronic HT	11.37 ± 3.73	16.87 ± 2.79	24.00 ± 4.14	<0.001(S)
PIH	14.44 ± 7.23	22.33 ± 6.63	28.88 ± 7.21	0.001(S)
P value	0.535(NS)	0.252(NS)	0.495(NS)	

Table 4: Association of Prothrombin Time (sec) with BMI, Glycemic status & blood pressure status

Trimester	Prothrombin Time (sec)			P value
	First	Second	Third	
BMI (kg/m²) (Mean ± SD)				
<18.5 (n=2)	11.87 ± 1.12	12.62 ± 1.40	12.12 ± 1.24	0.494 (NS)
18.5-24.9 (n=38)	12.90 ± 1.45	12.27 ± 1.55	11.99 ± 1.42	0.001(S)
≥24.9 (n=10)	13.73 ± 1.29	12.15 ± 1.56	11.65 ± 1.81	<0.001(S)
P value	0.006(S)	0.763 (NS)	0.619 (NS)	
Glycemic status (blood sugar level) (Mean ± SD)				
<126mg/dl	13.06 ± 1.45	12.25 ± 1.53	11.84 ± 1.48	0.016(S)
≥126mg/dl	12.7 ± 1.52	12.38 ± 1.56	12.29 ± 1.49	0.224(NS)
p-value	0.342(NS)	0.724(NS)	0.226(NS)	
Blood pressure status				
Normotensive	13.04 ± 1.53	12.27 ± 1.52	11.96 ± 1.52	<0.001(S)
Chronic HT	12.50 ± 0.53	12.00 ± 1.41	11.87 ± 1.64	0.598(NS)
PIH	12.88 ± 1.36	12.55 ± 1.81	11.66 ± 1.11	0.206(NS)
P value	0.597(NS)	0.760(NS)	0.842(NS)	

Table 5: Correlations of INR

Variables	1st trimester		2nd trimester		Third trimester	
	R	P value	r	P value	r	P value
BMI	0.019	0.855	0.066	0.515	0.156	0.121
B Sugar	-0.216	0.031 (S)	-0.135	0.179	-0.038	0.705
SBP	0.124	0.221	0.189	0.060	0.056	0.581
DBP	0.126	0.210	0.058	0.565	-0.040	0.692
MAP	0.135	0.181	0.111	0.273	-0.011	0.999

Table 6: Correlations of aPTT

Variables	1st trimester		2nd trimester		Third trimester	
	R	P value	r	P value	r	P value
BMI	0.003	0.978	-0.152	0.130	-0.034	0.740
B Sugar	-0.193	0.054	-0.120	0.233	0.030	0.766
SBP	-0.208	0.037 (S)	0.134	0.183	-0.050	0.623
DBP	0.254	0.001 (S)	0.086	0.395	-0.127	0.280
MAP	-0.255	0.010 (S)	0.110	0.277	-0.099	0.326

The pregnant women those had BMI 18.5-24.9 Kg/m² and BMI ≥ 24.9 Kg/m², D-dimer level was increased significantly from first trimester to third trimester (P<0.001). D-Dimer level was increase in both hyperglycaemic and normoglycemic (P<0.001). while comparing in same trimester there was no significant difference was found (p value in all three trimester 0.129, 0.113, 0.144 respectively in all three trimester). D-Dimer was increased from first to third trimester of pregnancy in patients with all Hypertensive as well as normotensive but statically significant only in normotensive and pregnancy induced hypertension (PIH) (P<0.05). It shows that well controlled blood pressure in chronic hypertensive patients (who was on antihypertensive drug) had no significant effect on D-dimer level. Only elevated blood pressure affects the D-dimer. (Table 2)

FDP was increased in all BMI groups pregnant women (p <0.001) but in same trimester it was significant only in first (p<0.008) and second trimester (p<0.046). In same trimester only third trimester, the FDP was significantly higher in patients with blood sugar >126mg/dl (P=0.049). On comparison in the same trimester (p-0.535, p-0.252, p-0.495 respectively) no significant difference was found in FDP level across all BP status. (Table 3)

Prothrombin time was decline from first to third trimester of pregnancy in patients with BMI 18.5-24.9 Kg/m² and BMI ≥24.9 Kg/m² (P=0.001). On comparison in the same trimester, only in first trimester however there was increase in Prothrombin time with increasing BMI (P=0.006). PT was decreased from first to third trimester of pregnancy only in patients with normoglycemic status (P<0.001). PT was decreased from first to third trimester of pregnancy in patients with all blood pressure status but significantly decline only in normotensive patients (P<0.001). On comparison in the same trimester (p=0.597, p=0.760, p=0.842) however no significant difference was found. (Table 4)

INR was increase from first to third trimester of pregnancy in patients with all BMI groups (p < 0.003). On comparison in the same trimester, no significant difference was found (p=0.451, p=0.345, p=0.512). There was increase in INR from first to third

trimester of pregnancy in patients with all glycemic status (p<0.001). There was increase in INR from first to third trimester of pregnancy in patients with all Blood pressure status, significant only in normotensive and PIH patients (P<0.001). On comparison in the same trimester (p=0.829, p=0.953, p=0.947), no significant difference was found. (Table 5)

The aPTT was declined from first to third trimester of pregnancy in patients with all BMI groups and significant only in BMI 18.5-24.9 Kg/m^2 and BMI ≥24.9 Kg/m^2 group (P<0.05). On comparison in the same trimester (p=0.637, p=0.340, p=0.741, no significant difference was found in aPTT. There was decline in aPTT from first to third trimester of pregnancy in patients with any glycemic status (P<0.001). On comparison in the same trimester (p=0.391, p=0.724, p=0.130), no significant difference was found in aPTT. On comparison in the same trimester, only first trimester (p=0.019) had significant difference was found in aPTT. (Table 6)

DISCUSSION

The present study showed that the mean ages of pregnant women were 26.4 years. Federico et al[8] studies on coagulation profile in pregnant women with mean age 28.7±4.13 years (age range 22-41 years). Zaccheus et al[9] conducted study in pregnant ladies with mean age 28.4±4.2 years (age range 16-41 years).

The D-Dimer level was increase with gestational age. Highest level would be seen in third trimester. On comparison in all trimesters, significant (P<0.001) increase was seen between all trimesters. The incidence of elevated D-dimer was found in 55%, 65% and 78% women in first, second and third trimester respectively. Kovac et al[10] concluded that 16% of women had an abnormal concentration of D-Dimer in first trimester, 67% had abnormal concentration in second trimester and just 99% had an abnormal concentration by the third trimester. Comparing with our study this study had been included pregnant women who had suspected VTE and previous complicated deliveries resulting in higher prevalence of elevated D-dimer levels. Another study done by N Murphy et al[11] concluded that an abnormal D-dimer concentration first trimester had 19%, second trimester had 94% and third trimester had 100% abnormal concentration. This difference from our study because in this study majority of women were multiparous (62.3%) which was just double as compare to our study (31%), and sample size was large (n=760). Santoshi et al[12] conducted a study on changes in d-dimer levels according to the stage of pregnancy. The d-dimer (µg/mL) in the 1182 women without clinical VTE, at gestational week (GW) 4, 13, 27, 35 the d dimer level was 0.54, 2.41, 5.03, 6.18 respectively. 33% (3/9) with a d-dimer level 14µg/mL developed clinical VTE, while none of the remaining 1176 women with a d-dimer level ⩽14 µg/mL developed clinical VTE. This study result was similar to our study that there was increase in D-Dimer concentration. Naveed Sattar et al[13] conducted a study (1991) in which they had taken pregnant women who had 10 weeks gestation (± 1 week) and thereafter at five weeks intervals until 35 weeks of pregnancy and found increase in median D-dimer concentration by more than 4-fold (68.5 to 295.5 ng/ml) (p<0.001).

In our study an abnormal FDP concentration in first, second and third trimester were 93%, 99% and 100% respectively. In a similar study, Imoru Momodu et al[14] conducted a study on fibrinolytic activity during pregnancy and showed that pregnant women had significantly higher values of FDP 6.17µg/mL±12.4, 8.15µg/mL±9.4, 10.17µg/mL±15.08 compared to 2.8±7.63 µg/mL, in non-pregnant women (*P*<0.005). This finding match with our study results as in both study there was statistically significant increase in FDP levels.

The Prothrombin time was decline with subsequent trimesters (P<0.001). Lowest value was seen in third trimester. Comparison of all three trimester, significant decline was seen between first trimesters v/s second and third trimester, but decline from second to third trimester was not statistically significant (P>0.001). In our study elevated prothrombin time in first, second and third trimesters were 17%,10% and 5% respectively.

Tashin Mushtaque et al[15] (2013) study revealed the mean prothrombin time for normal pregnancy, non-severe PIH and severe PIH patients were 10.9 seconds, 10.1 seconds and 9.8 seconds respectively, with P-value less than 0.0001 was statistically significant. Pannala et al[16] studies on coagulation profile in pregnancy in 50 healthy pregnant women and showed that the control group has a mean Prothrombin Time of 9.16 sec with SD of ±1.10 whereas the test group showed a mean Prothrombin Time of 14.32 Sec and SD of ±1.91, P <0.001 and concluded that there was decline in prothrombin time in subsequent trimesters. Xing-hui Liu et al[17] conducted a prospective, sequential, longitudinal study in consecutive participants attending a prenatal clinic at West China Second University Hospital with 232 Chinese women. In this study PT-INR, aPTT were shorter, and platelet count decreased gradually during pregnancy. The results of above studies are similar to present study.

The mean aPTT value (sec) was 36.57±2.62 35.37±2.60 34.37±3.01 in first, second and third trimester respectively and also declined with advance gestational age. On multiple comparison of each trimester there was statistically significant (P<0.001) decrease in aPPT value. The prevalence of shortened aPTT in first, second and third trimesters were 3%, 2% and 2% respectively. Sarika Singh et al[18] conducted a retrospective study in tertiary care hospital in North India among pregnant women and found 37.6% had shortened aPTT. Most (83%) of the patients were in their 3rd trimester of pregnancy during which the highest prevalence of shortened aPTT is seen.

The results of this study showed that coagulation trends in all three trimesters of pregnancy and also correlate them with blood pressure status (normotensive, chronic hypertensive and pregnancy induced hypertension) and blood sugar status. FDP, D-Dimer, APLA and INR are increased while platelets counts, PT and aPPT was declined.

CONCLUSION

We concluded that there was a increased in FDP, D-Dimer, INR, APLA while platelets count, PT and aPTT were decreased. This study constituted a platform for such larger studies.

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