Original Research Paper

Volume - 11 | Issue - 09 | September - 2021 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Obstetric & Gynaecology

COMPARATIVE STUDY OF FIBRINOGEN LEVEL IN NORMAL PREGNANCY, HYPERTENSIVE DISORDERS OF PREGNANCY AND INTRAUTERINE FOETAL DEATH.

Dr Saloni* *Corresponding Author

Prof. Sarita Tirkey

Dr Prashant Raman

ABSTRACT **Introduction:** Haemostatic failure as a result of Obstetric complication of hypertensive disorders of pregnancy and intrauterine foetal death is an important cause of maternal mortality and morbidity. The assessment of the coagulation parameters is important to diagnose the severity of the disease. **Aims and Objectives-**To compare serum fibrinogen in normal pregnancy and in hypertensive disorder of pregnancy and intrauterine foetal death. **Materials and Methods:** This study was conducted in the department of Obstetrics and Gynaecology, RIMS, Ranchi during the period of April'16 to September'17. A total of 450 patients after 28 weeks of gestation were taken for the study. 150 were cases of hypertensive disorder of pregnancy and 150 were intrauterine foetal death. 150 patients were taken as control for the comparative analysis.**Results:** The fibrinogen levels in present study decreased significantly in patients with hypertensive disorder of pregnancy and IUD. The mean value of fibrinogen in normal patient was 446.72±38.35 mg/dl, in patients with hypertensive disorder of pregnancy was 413.96±74.07 mg/dl and in patients with IUD was 360.07±95.23mg/dl. There was a significant difference noted in routine blood parameters such as Haemoglobin, Platelets and Total Leucocyte count in study group. The coagulation profile was also found to be deranged in the study population. The maternal and perinatal outcome in PIH and IUD was worse than in control group. **Conclusion:** The estimation of plasma fibrinogen is helpful not only in the early diagnosis of haemostatic failure but also to guide replacement therapy during the fibrinogen depletive state.

KEYWORDS :

Introduction:

The dangers surrounding obstetrical disseminated intravascular coagulation were recognized and described as early as 1901 in the obstetrical literature, when Joseph De Lee first reported a fatal case of hemorrhagic diathesis with placental abruption.[1]

Globally, an estimated 287 000 maternal deaths occurred in 2010 with India contributing 19% (56 000). The MMR in developing regions (240) was 15 times higher than in developed regions (16).[2]According to WHO project report 2014, DIC is associated with 25% of maternal death.

Normal physiology of blood clotting mechanism as well as physiological changes in pregnancy is required to understand the abnormalities of coagulation**.** Pregnancy is a complex physiological process with increased coagulation factors and decreased anti-coagulation factors leading to ***"hypercoagulable state".*** There is gross elevation of plasma fibrinogen levels in pregnancy especially in third trimester.

- Normal plasma fibrinogen level is 200-450mg/dl
- Plasma fibrinogen level in normal pregnancy is 300-600mg/dl

Consumptive coagulopathy or DIC is a serious complication due to abnormality in hemostasis. It is characterised by widespread intravascular fibrin deposition in response to excessive blood protease activity that overcomes the anti-coagulant mechanism. Levels of fibrinogen below 100 mg/dl is associated with overt DIC.[3]

Antecedent causes of consumptive coagulopathy in obstetrics are[3,4].
1. Placental abruption
2. Foetal death
3. Preeclampsia syndrome
4. Septic abortion
5. Amniotic fluid embolism

In this study, plasma fibrinogen level was compared in normal pregnancy with hypertensive disorders of pregnancy and in patients with intrauterine foetal death.

Materials and methods: The study was conducted at the Department of Obstetrics and Gynaecology, Rajendra Institute of Medical Sciences (RIMS), Ranchi during the period April 2016 to October 2017.

Study design: This was a comparative study of plasma fibrinogen level on 150 patients each of normal pregnancy, hypertensive disorder of pregnancy and intrauterine foetal death after 28 week of gestation. This study was carried out in RIMS on patients randomly selected from labour room (emergency) and Obstetrics & Gynaecology OPD during April 2016 to October 2017.

Inclusion criteria:
- Normal pregnant women (after 28 week of gestation)
- Pregnant women with hypertensive disorder of pregnancy (after 28 week of gestation) were included in this study. They were further subdivided into mild (BP<160/110 mm of Hg) and severe(>160/110mm of Hg).
- Pregnant women with intrauterine fetal death after 28 week of gestation.

Exclusion criteria:
- Pregnant women with known bleeding disorder
- Patients on anticoagulant therapy
- Patients with pre-existing medical conditions involving liver, heart, kidney or other co-morbidities.
- History of chronic hypertension , history of Diabetes.

In the study fibrinogen was estimated by Clauss' method.
The patients were evaluated according to routine clinical examination and investigations.

Statistical analysis: Mean and standard deviation of different groups were calculated. The statistical significance were calculated using Student t-test. Median of the data was calculated when required. P value less than 0.05 was considered significant.

Observation:

Table 1. Patient demographics.

Parity	Normal patients		PIH		IUD	
	Number	%	Number	%	Number	%
Primigravida	64	42.67%	98	65.33%	60	40%
Second gravida	43	28.67%	24	16%	31	20.67 %
Others	43	28.67%	28	18.67%	59	39.33 %

Table 2. Lab investigation of the cohort.

Blood Investigation	Normal Patients	Hypertensive disorders of pregnancy	IUD
Hb	10.51g/dl	10.08g/dl	8.57g/dl
		T stat:2.9644 P value:0.0016	T stat:9.8671 P value:<0.0001
Total count	10,638/cu.mm	12,642/cu.mm	12,802/cu.mm
		T stat:-2.0724 P value:0.0195	T stat:-2.2591 P value:0.0123
Platelets	2.32	2.05	2.09
		T stat:4.6260 P value:0.0047	T stat:3.4234 P valu0.0004e:
Bleeding Time	57.43s	63.80s	76.17s
		T stat:-2.6122 P value:0.0047	T stat:-4.6879 P value:<0.0001
Clotting Time	220.87s	236.17	247.83
		T stat:-3.7322 P value:0.0001	T stat:-3.9233 P value:0.0001
INR	1.00	1.28	1.34
		T stat:-13.1597 P value:<0.0001	T stat:-12.9185 P value:<0.0001

There was a statistically significant difference noted in the mean Hb between patients with hypertensive disorder and IUD. Similar alterations were noted in total leucocyte count, platelets and coagulation parameters as well.

Table 3. Serum fibrinogen levels in the different cohorts.

Fibrinogen level	Normal patients	Hypertensive disorder of pregnancy	IUD
Mean	446.72mg/dl	413.96mg/dl	360.07mg/dl
Median	440mg/dl	416mg/dl	386.75mg/dl
Standard Deviation	38.35	74.07	95.23
T Value		4.8110	10.3375
P Value		<0.0001	<0.0001

In normal patients all the patient had serum fibrinogen in the range 300-600mg/dl whereas 5% patients in hypertensive group and almost 19% patients in IUD group had reduced Sr. Fibrinogen level

Table 4: Mean and central distribution of Sr. Fibrinogen level in different cohorts.

Fibrinogen level	Normal patients		PIH		IUD	
	Number	%	Number	%	Number	%
300-600mg/dl	150	100%	142	94.67%	122	81.33%
150-300mg/dl	0	0%	7	4.67%	23	15.33%
<150mg/dl	0	0%	1	0.67%	5	3.33%

Serum fibrinogen levels were statistically significantly reduced in the patients with hypertensive disorder of pregnancy and in the patients with IUD in comparison to the control group.

Discussion:

1. In the present study it was found that majority of the patients in the hypertensive disorder of pregnancy group were primigravida (65.33%), 16% were second gravida and others were 18.67%.

The result found in the study was comparable to the studies by Asiya Naz[10](2015), Chaware SA[13](2015), Raji C[17]. In my study of IUD group primigravida were 40%, second gravida were 20.67% and others were 39.33%. The proportion of multigravida was higher (60% i.e. 20.67 + 39.33). Divya B[12](2015) found similar proportion in her study with multigravida constituting 60.8% of the total patients with IUD. The control group in the study had 42.67% primigravida, second gravid were 28.67% and others were 28.67%.

2. Platelets count for the three groups in the study were 2.32±0.55 lakh/cu.mm, 2.05±0.44lakh/cu.mm and 2.09±0.63lakh/cu.mm respectively in the present study. The platelet count ranged from 1.05-4.05 lakh/cu.mm in the hypertensive group and 0.66 -5.02 lakh/cu.mm The results were statistically significant. Thakur Bhavana et al[15](2016) found that there is an inverse relationship between the severity of PIH and platelet count.

3. In this study mean bleeding time in the control group was found to be 57.43±18.37s, hypertensive disorder of pregnancy was 63.80±23.55s and IUD group was 76.17±45.37s.The range of bleeding time for the PIH patients was found to be 30-150s and for IUD group was 30-300s.

4. Mean clotting time in control group was 220.87±26.18s, for hypertensive disorder of pregnancy was 236.17±42.85s and IUD group was 247.83±80.01s.

Range of clotting time in the study for PIH group was 165-450s and it was 120-680s in the IUD group.

Mean PT-INR was 1.28 for hypertensive disorder of pregnancy group , 1.34 for the IUD group and 1.00 for the control group in my study. The results were statistically significant.

The result of coagulation profile was similar to that reported by Tempfer CB8(2009), Joshi SR11(2015), Chaware SA13(2015) and Sharma U[16](2016).

5. In my study most of the patient in hypertensive disorder of pregnancy had normal fibrinogen i.e 300-600mg/dl), 7(4.67%) patient had decrease in fibrinogen level in the range of 150-300mg/dl while in 1(0.67%) patient fibrinogen markedly decreased to below 150mg/d.

6. IUD group in the study had 122 patients with fibrinogen in the range 300-600mg/dl, 23 in range 150-300mg/dl and 5 had fibrinogen level below 150mg/dl. Serum fibrinogen decreased significantly in the patients with hypertensive disorder of pregnancy and in the patients with IUD, in comparison to the control group in this study. H.Parsnis [5](1992) found in his study that 30 patients out of 133 prone to develop DIC, had fibrinogen in the range 150-300mg/dl and 8 patients had fibrinogen level below 150mg/dl. Tahani Abbas Mohamed et al(2016)[14]concluded that fibrinogen level of <150–200 mg/ dl is associated with tendency for bleeding. In my study the mean value of fibrinogen in normal patient was 446.72±38.35 mg/dl, in patients with hypertensive disorder of pregnancy was 413.96±74.07 mg/dl and in patients with IUD was 360.07±95.23mg/dl. In the study conducted by Kanchana A [18] (2016) showed a decrease in the fibrinogen level. The mean value of fibrinogen in PIH was 296.0 ±48.03mg/dl and in IUFD was 262.4±20.06, according to her. She reported that the mean value in the control group was 442±43.38mg/dl. It was similar to the present study. Similar findings were reported in other studies by H.Parsnis[5](1992), MPFitzgerald[7](1996), Maslow AD[6](1996) . In this study DIC developed in 2(1.33%) patient of the hypertensive disorder of pregnancy group and in the case of IUD group coagulopathy occurred in 5(3.33%) while overt DIC developed in 1(0.67%) patient.

7. The coagulation profile was found to be deranged in this study, in both PIH and IUD group but it was more deranged in IUD group. Therefore the number of patients with IUD required more blood and blood product transfusion.

In the study by Rattray D[9](2012) reported that massive transfusion of blood and blood products was required in 3 patients with DIC out of 72.

Conclusion:

- The study concludes that coagulopathy, though not a very frequent complication but it is still a very severe complication. One has to be very vigilant during antenatal and perinatal period for early detection of risk factors and its timely management
- In high risk patients, susceptible to develop coagulopathy, estimation of serum fibrinogen is suggested in the 3rd trimester for early detection of haemostatic failure.
- The estimation of plasma fibrinogen is helpful not only in the early diagnosis of hemostatic failure but also guides replacement therapy
- Fibrinogen level estimation will improve the maternal and fetal outcome and will reduce the burden of hospital resources like prolonged hospital stay, blood &blood products etc.

Acknowledgement: This is my humble privilege to express my heartfelt gratitude and compliment to my revered teacher and guide Dr. (Professor.) SARITA TIRKEY, MBBS, MD, Department of Obstetrics and Gynaecology, Rajendra Institute of Medical Sciences, Ranchi, for her constant encouragement and valuable guidance. Throughout the course of this work, she was a constant source of inspiration. I would like thank my "parents", Mr. A.N.Sinha & Mrs. Nita Sinha, Mr.

I.B.Sahay & Dr. K.L.Sinha who stood on my either side throughout my endeavour. Specially, I would like to name my brother Er. Satyam Sidharth for providing me with all the support for the completion of the project! I feel privileged to remember all the love and affection of my dear family members.

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