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Maternal And Neonatal Outcome In Women With Vaginal Bleeding During First Trimester Of Pregnancy: A Prospective Observational Study

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Abstract:
Background First *trimester miscarriage is a Common occurrence in obstetric practice. It is one of the common reasons for Emergency room visits in early pregnancy. Sub chorionic haematomas was considered as a prognostic factor. In this study we were looking into this aspect and also pregnancy and neonatal out come.*
Materials and Methods*: The study is for a period of 18 months from January 2021 to June 2022 and is designed as a prospective observational study in the obstetrics and gynecology department at KIMS HEALTH Trivandrum, Kerala. Patients of first trimester vaginal bleeding will be identified during ER calls and in Gynecology, OPD A total of 104 pregnant women in the age group of 20 to 40 years with bleeding per vaginum in the first trimester attending OPD/ ER or inpatients in the department of Obstetrics and Gynecology, KIMSHEALTH hospital, Kerala, India were enrolled in this 18 months observational study. Pregnant women with any comorbidities, bleeding disorders, or ectopic pregnancy were excluded from the study*
Results: *It was concluded that in this study, pregnant patients who had a sub chorionic hematoma in the first trimester had greater chances of bleeding in the second trimester and second trimester abortion with a significant p-value of <0.001 and <0.026 respectively:*
Conclusion: *we could conclude that sub chorionic bleed itself is not a poor prognostic indicator in pregnancy with first trimester vaginal bleeding.*
Key Word*: Miscarriage: Sub chorionic hematoma: First trimester: second Trimester*

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I. Introduction

First trimester vaginal bleeding is one of the most common obstetric problems. It is defined as any discharge of blood from the vagina before completed 12 weeks. Nearly 25% of all pregnant women in their first-trimester experience this alarming event. [1, 2] It is also one of the commonest causes of Emergency room visits and admissions. Approximately one-third of first-trimester vaginal bleeding happens in otherwise normal pregnancies [3] In addition, the anatomical cause can be recognized in the majority of pregnancies that are complicated by vaginal bleeding with the help of the ultrasound(US) in the modern era [4]. Half of the women who experience first trimester vaginal bleeding will carry on with their pregnancies and the other half be having an abortion. [4] If the pregnancy continues poor maternal and fetal outcomes like preterm delivery, Preterm Premature rupture of membranes (PPROM), placental abruption, pre-eclampsia, and Intrauterine growth retardation (IUGR) are observed[7]

Miscarriage, ectopic, implantation bleeding of pregnancy, and cervical pathology. [5] are four major recognized causes. The outcome may be probably affected by the gestational age of the bleeding, the cause of the bleeding, and the severity of the bleeding. [6]. After taking a detailed history, physical examination, and pelvic examination, imaging techniques, diagnosis, and plan of management are decided usually.

It is one sign of pregnancy risk, the patient observes directly. However, the outcome of bleeding per vagina (PVB) in pregnancy is often not predictable. Whereas many cases of PVB are only a benign event, some are a feature of early pregnancy failure while others are an indication of later pregnancy complications. Spotting is bleeding reported by the patient as scant or traces of blood or visualized by clinician as scant or no blood in vagina and at the cervix. Light bleeding is reported by the patient as like a 'menses'. It is visualized by the clinician as a small amount of blood in vagina or at the cervix. Heavy bleeding is reported by the patient as more than a 'menses'. It is visualized as a moderate to heavy amount of blood in vagina or at the Cervix. [51])

It is also known that maternal age, systemic diseases such as diabetes mellitus, hypothyroidism, infertility treatment, thrombophilia, maternal weight, and uterine structural anomalies also increase the risk of abortus imminens[5].

Further, it is hypothesized that first trimester bleeding may indicate an underlying placental dysfunction, which may later be proven in pregnancy, as adverse outcomes such as the increased risk of pre-eclampsia toxemias, preterm delivery, prelabour rupture of membranes (PROM), and IUGR.[8]

The incidence of bleeding in pregnancy has a wide variation which depends on the stage of pregnancy. In the review work by Olugbenga and associates in 2019, the incidence was reported to be 12% to 40%. [10] Other researchers have previously documented [11, 12] 20% to 30% and 3.75% in late pregnancy, with higher incidence found in earlier stages [13] of pregnancy

The experience of PVB in pregnancy is associated with adverse pregnancy outcomes as shown by some investigators, and the sensitivity for predicting pregnancy complications increases with recurrent [10, 13, 14] PVB. Early complications documented in women who report PVB include miscarriage, ectopic gestation, and molar pregnancy. PVB may initially be supposed to announce implantation in some cases, but as the pregnancy progresses, it may become clear that the bleeding is from the genital tract or a feature of a systemic bleeding disorder, which is a rare presentation. In some cases, the bleeding may be subtle and often ignored or not reported by the woman. Importantly, implantation bleeding, evolving miscarriage, ectopic gestation or gestational trophoblastic disease may be difficult to differentiate at the earliest occurrence of PVB in the first trimester from [15- 17] genital tract lesions manifesting as PVB. Beyond the first trimester, PVB is often associated with the placenta, an observation that can be explained by the occurrence of chronic decidual inflammation, impaired placentation, oxidative stress, and perhaps the failure of invasion by spiral arterioles.[44] These abnormalities have been associated with miscarriages, fetal growth restriction, preterm birth, preeclampsia, and other adverse outcomes [18]. Previous investigators have been consistent in indicating a role for threatened miscarriage in the later development of antepartum hemorrhage and other forms of adverse pregnancy [19, 20] events

Moreover, the presence of intrauterine hematoma without obvious vaginal bleeding has also been reported in pregnancies subsequently found to present with an increased risk of miscarriage, preterm birth, small for gestational age fetuses, and hypertensive disorders of pregnancy. [18, 21, 22] Earlier researchers have documented up to 50% risk of miscarriage following the first trimesters of bleeding [23, 24]. Other adverse outcomes associated with early pregnancy PVB include preterm delivery, intrauterine growth restriction (IUGR), preterm premature rupture of membranes, and perinatal morbidity and mortality. [8,20,25] There is evidence to show that low birth weight is a complication of second-trimester bleeding.[26, 27] Increased interventions with induction of labor and Caesarean section are also found to be correlated with PVB in the second half of pregnancy. Furthermore, placental disorders associated with PVB such as placenta praevia and abruptio placentae are known to increase the risk of Caesarean section [28]. Placenta praevia is a major contributor to adverse maternal and perinatal outcomes [18]. The need to examine the role of early PVB in the development of complications like placenta praevia in our environment remains pertinent. Considering the important role of obstetric hemorrhage in maternal health and perinatal outcome, early detection of placenta praevia will be useful in alleviating the toll on maternal and perinatal health due to bleeding placenta praevia, such as maternal anemia, blood transfusion, preterm delivery, and maternal and perinatal mortality.

The purpose of this study is to investigate the effect of first trimester vaginal bleeding on maternal and neonatal outcomes. First trimester vaginal bleeding is a cause of anxiety for both mother and caretaker and so conclusions from this study can be used to counsel the patients regarding the outcome and also the associated risk factors.

II. Material And Methods

STUDY SITE

The study is designed as a prospective cohort study of pregnant women in the first trimester vaginal bleeding in the department of obstetrics and gynecology in KIMS HEALTH Trivandrum, between January 2021 and June 2022.

STUDY POPULATION

All pregnant women presenting to the Obstetrics and Gynecology OPD and ER in KIMS HEALTH, Trivandrum with first trimester vaginal spotting, moderate and heavy bleeding.

STUDY DESIGN

A prospective observational study

SAMPLE SIZE ESTIMATION:

n = $\dfrac{z^2 1-\frac{a}{2}p(1-p)}{d^2}$ Required sample size (n),

Z= 1.96(for 95% confidence interval)

P= 68.7% (Proportion of patients having first trimester vaginal bleeding on maternal outcome (Percent of full term normal delivery)) 8 q =1-p
Allowable error, d = 9%

Then, n= $\frac{(1.96)^2 x(0.687)x\ (1-0.687)}{0.0081}$

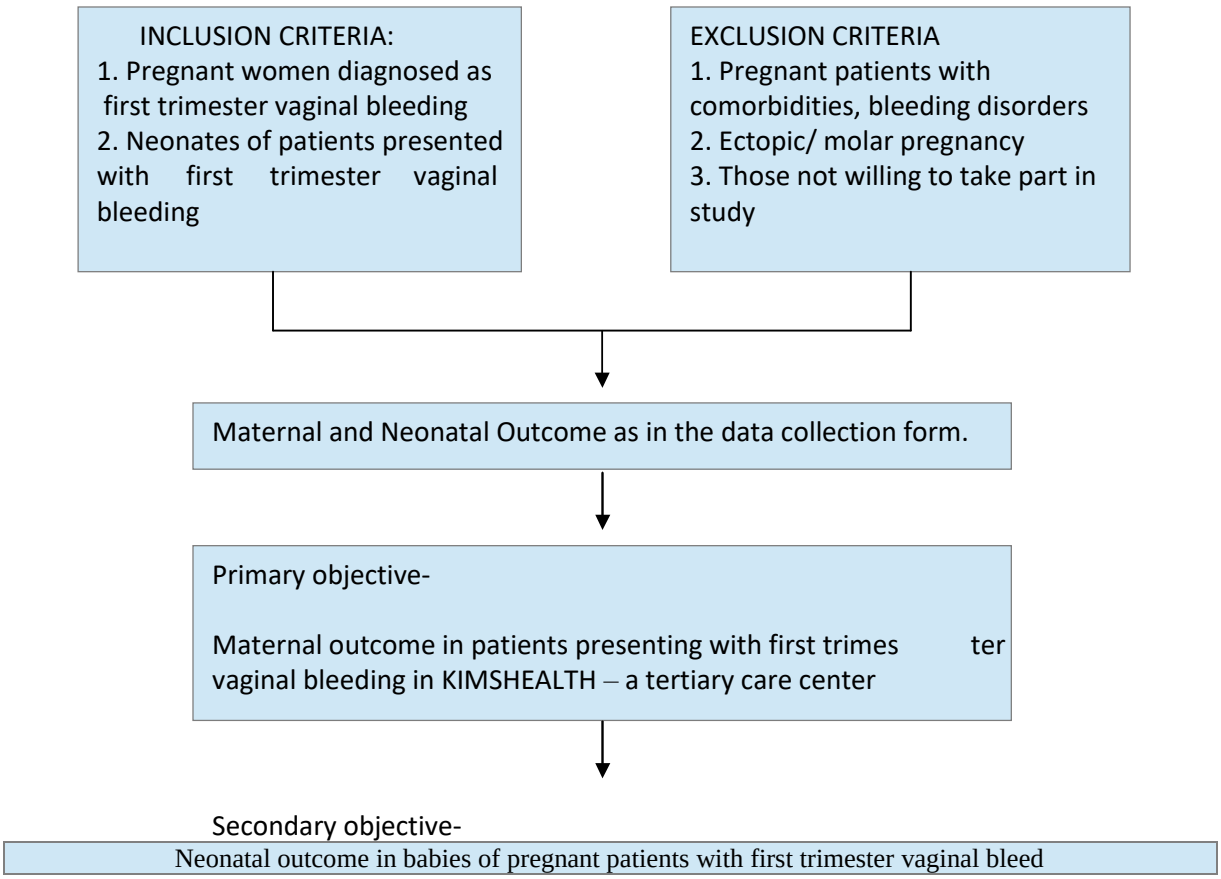
Required sample size n =104. Duration of the study was for 18 months from January 2021 to June 2022.All pregnant women with first trimester vaginal spotting, moderate and heavy bleeding were enrolled in the study and pregnant women with comorbidities and bleeding disorders, ectopic, molar pregnancy was excluded

The study is for a period of 18 months from January 2021 to June 2022 and is designed as a prospective observational study in the obstetrics and gynecology department at KIMS HEALTH Trivandrum, Kerala. Cases of first trimester vaginal bleeding will be identified during ER calls and in Gynecology, OPD. Pregnant women will be interviewed in detail after getting informed consent. All the cases will be followed up during their hospital stay in cases needing admissions, booked cases in OPD will be followed accordingly and patients not booked in the Gynecology department will be followed up personally over the phone till their delivery. The outcome of each case will be analyzed. For each case of first trimester vaginal bleeding, data will be collected on gestational age, gravida, whether pain abdomen was present at the time of presentation, gestational age at the time of bleeding, maternal age, pregnant women without medical disorders, nature of vaginal bleeding (whether spotting per vagina, bleeding per vagina or blood-stained vaginal discharge), and Ultrasound findings are taken into consideration. The data of the patients entered concerning admission/OP basis/ER using an interviewer-administered questionnaire, participant examination, investigations, and through review of medical records. The maternal and neonatal outcomes of these patients will be analyzed. The primary outcome of this study was to analyze the maternal outcome in women with vaginal bleeding in first trimester and secondary was to analyze neonatal outcome in same group.

DATA COLLECTION METHODS

All the data collected will be entered by the principal investigator in an interviewer-administered questionnaire. This proforma contains relevant clinical history, examination findings, and investigation details.

STUDY FLOW CHART



STATISTICAL METHODS:

All data will be entered into MS Excel and analyzed using the statistical software SPSS version 16.0. Descriptive statistics will be summarized using Means with standard deviations (SD) or Median with inter-quartile ranges (IQR) for continuous variables and percentiles and rates for categorical variables.

ETHICAL CONSIDERATIONS:

Institutional ethics committee clearance will be obtained. Informed consent will be obtained from all the patients

III. Result

A total of 104 pregnant women in the age group of 20 to 40 years with bleeding per vaginum in the first trimester attending OPD/ ER or inpatients in the department of Obstetrics and Gynecology, KIMSHEALTH hospital, Kerala, India were enrolled in this 18 months observational study.

Pregnant women with any comorbidities, bleeding disorders, or ectopic pregnancy were excluded from the study.

Observations made are as follows:

Most patients were in the age group of 26- 30 years (39.4%), followed by 31- 35 years (37.5%).

The least number were in the age group of 36-40 years (9.6%), and age group < 20 years (13.5%).

The mean age of the patients was 30 years with a range of 19 – 39 years

(Table 1).

Age in years	Frequency	Percent
<25	14	13.5
26-30	41	39.4
31-35	39	37.5
36-40	10	9.6
Total	104	100

Table 2: Distribution of patients according to age (n= 104)

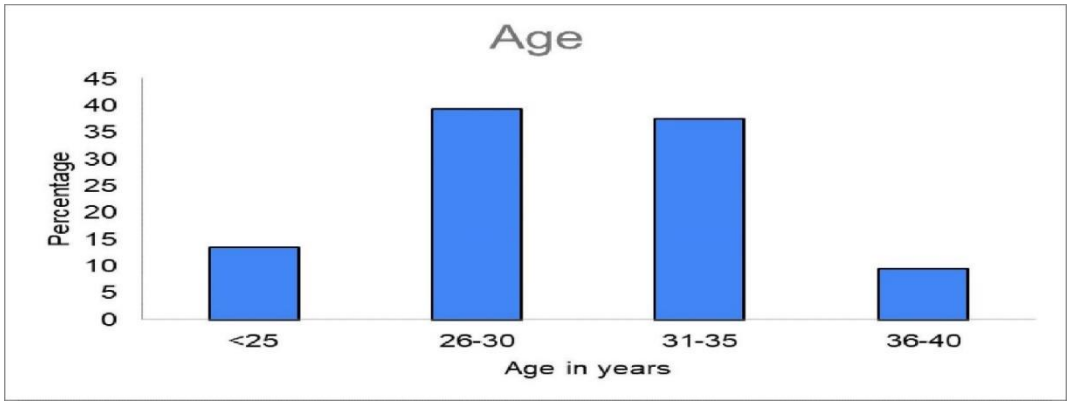


Figure no: 1: Age distribution

Most of the patients were normal (40.4%), with overweight (38.5%).At least were obese (21.2%). Mean BMI: 26.8% with a range of 18.6 to 36.8.

BMI	Frequency	Percent
Normal (18.5 – 24.9)	42	40.4
Over weight (25- 29.9)	40	38.5
Obese (≥30)	22	21.2
Total	104	100

Table 3: Distribution of patients according to BMI (n= 104)

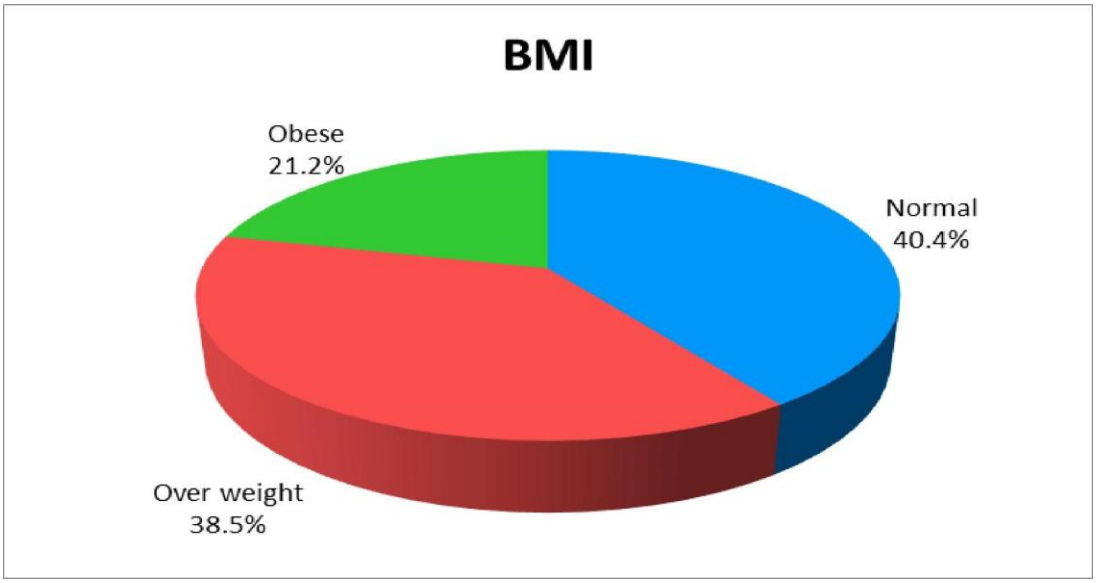


Figure no:2: BMI

Most of the patients were primi (60.6%), and multi constituted 39.4%.

PARITY	Frequency	Percent
Primi	63	60.6
Multi	41	39.4
Total	104	100

Table 4: Distribution of patients according to parity

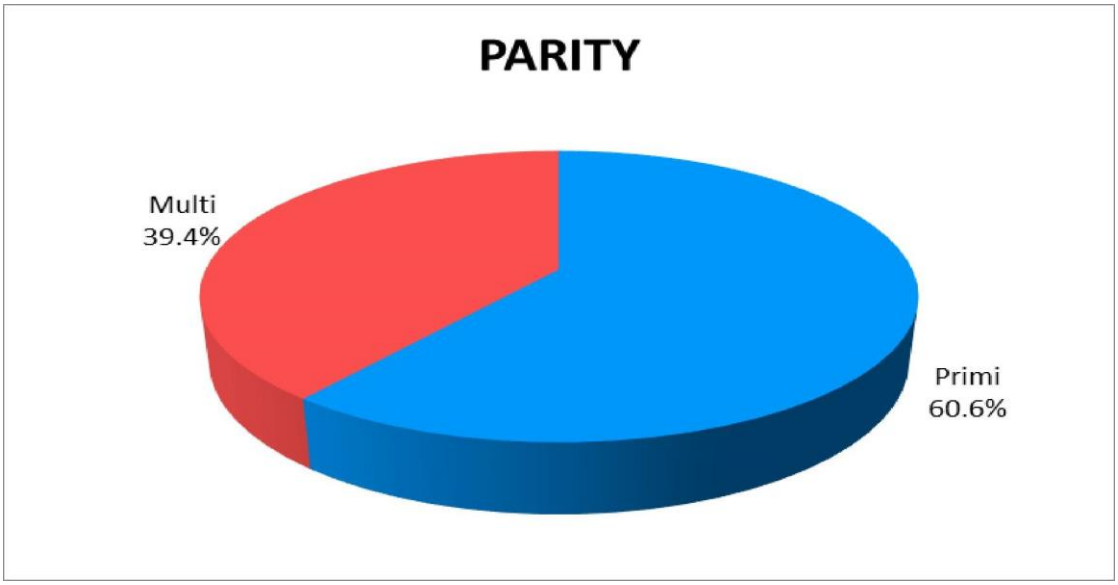


Figure no 3: Parity

The majority of the patients who presented with bleeding were in a range of 6- 10 weeks (61.5%), followed by > 10 weeks (21.2%), and <6 weeks (17.3%).

Gestational age at the time of presentation of bleeding	Frequency	Percent
<6	18	17.3
6-10	64	61.5
>10	22	21.2
Total	104	100

Table 5: Distribution of patients according to gestational age at bleeding.

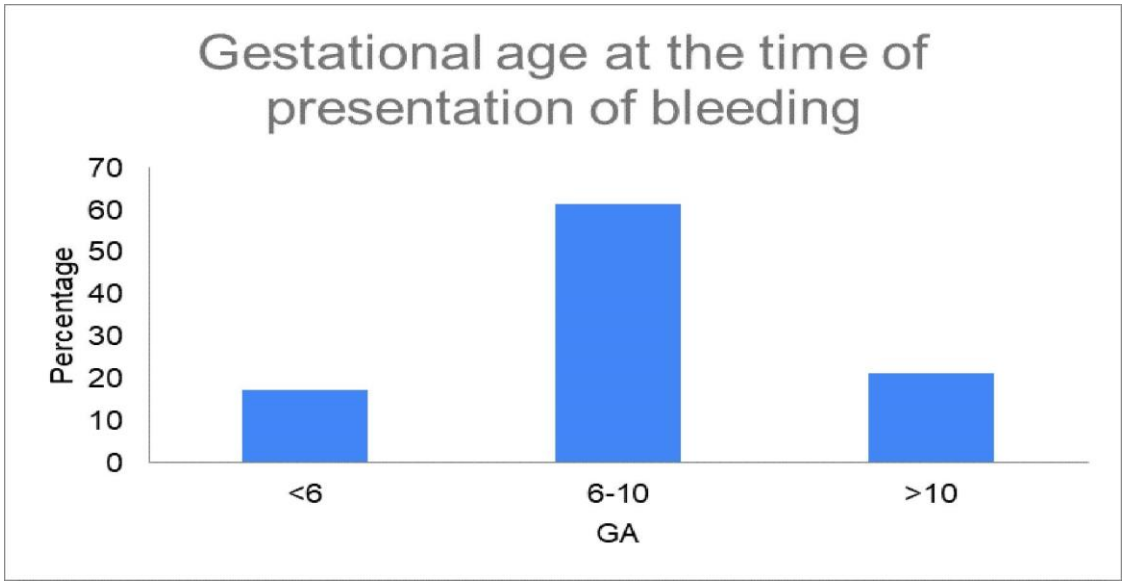


Figure no 4: Gestational age at the bleeding

Majority of the patients (53.8%) presented with spotting PV followed by moderate bleeding (35.6%) and heavy bleeding (10.6%).

COMPLAINTS	Frequency	Percent
Spotting	56	53.8
Moderate bleeding	37	35.6
Heavy bleeding	11	10.6
Total	104	100

Table 6: Distribution of patients according to the type of bleeding (n= 104)

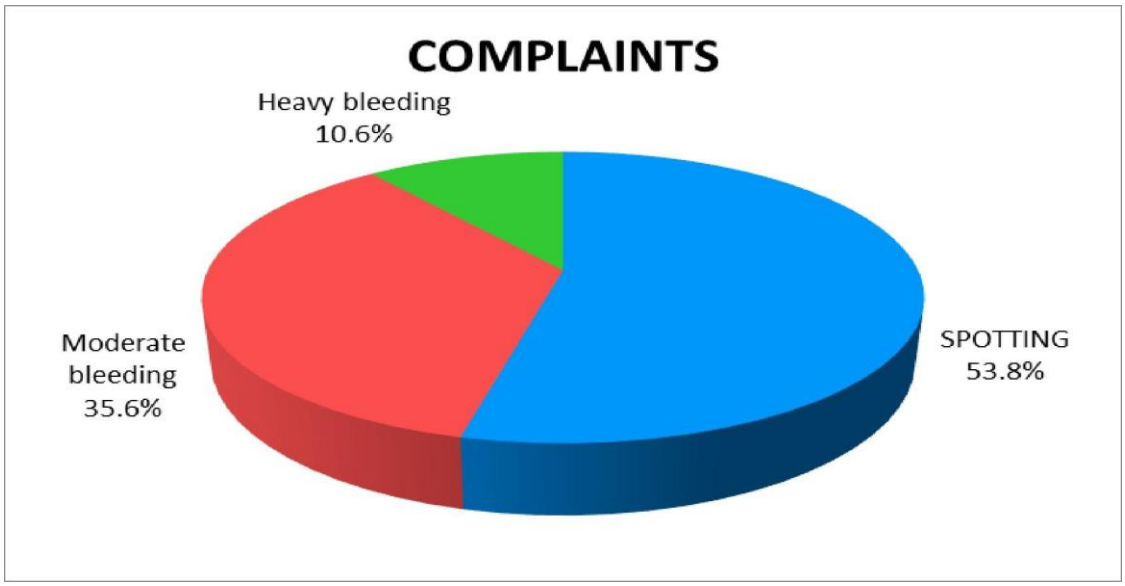


Figure no 5: complaints of the patients

Out of the 104 patients with first trimester vaginal bleeding, 30.8 % had sub chorionic hematoma.

SCH	Frequency	Percent
Yes	32	30.8
No	72	69.2
Total	104	100

Table 7: Distribution of patients according to the presence of subchorionic hematoma

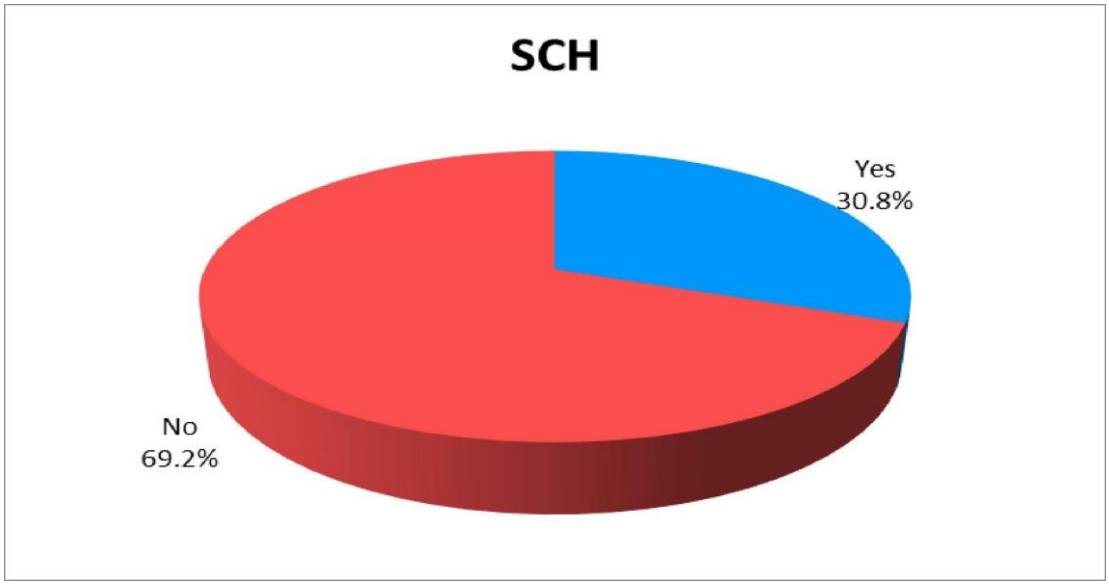


Figure no 6: Subchorionic hematoma

Out of the 104 patients, 27.9 % ended up with abortion, 72.1% continued there pregnancies

OUTCOME OF BLEEDING	Frequency	Percent
Abortion	29	27.9
Continued Pregnancy	75	72.1
Total	104	100

Table 8: Distribution of patients according to the outcome of bleeding

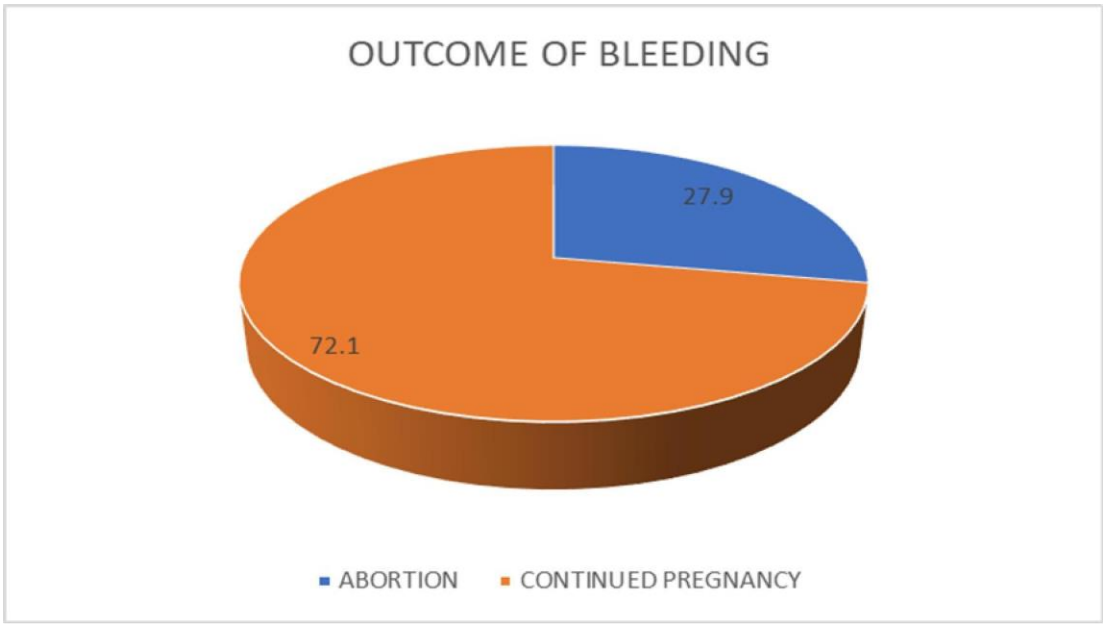


Figure no 7: Outcome of bleeding

Of patients who experienced a first-trimester bleed, only 15.4% had bleeding in the second trimester.

SECOND TRIMESTER BLEED	Frequency	Percent
Yes	16	15.4
No	88	84.6
Total	104	100

Table 9: Distribution of patients according to bleeding in the second trimester

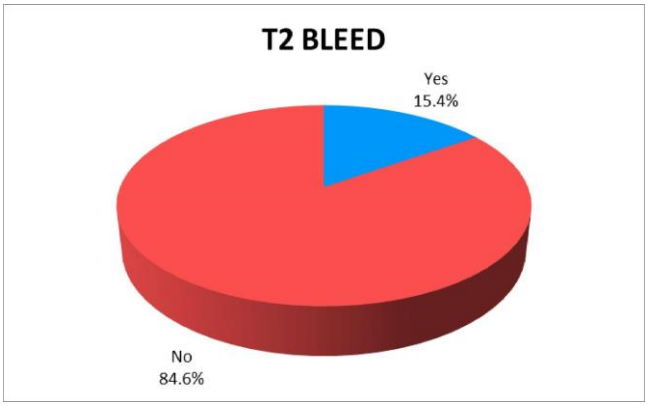


Figure no 8: Patients with the second trimester bleeding

Out of 75 patients who continued pregnancy, only 3 had third-trimester bleed (3.1%), Out of that abruption constituted 2 (2.1%)

THIRD TRIMESTER BLEED	Frequency	Percent
Yes	3	4
No	72	96
Total	75	100

Table 10: Distribution of patients according to bleeding in the third trimester

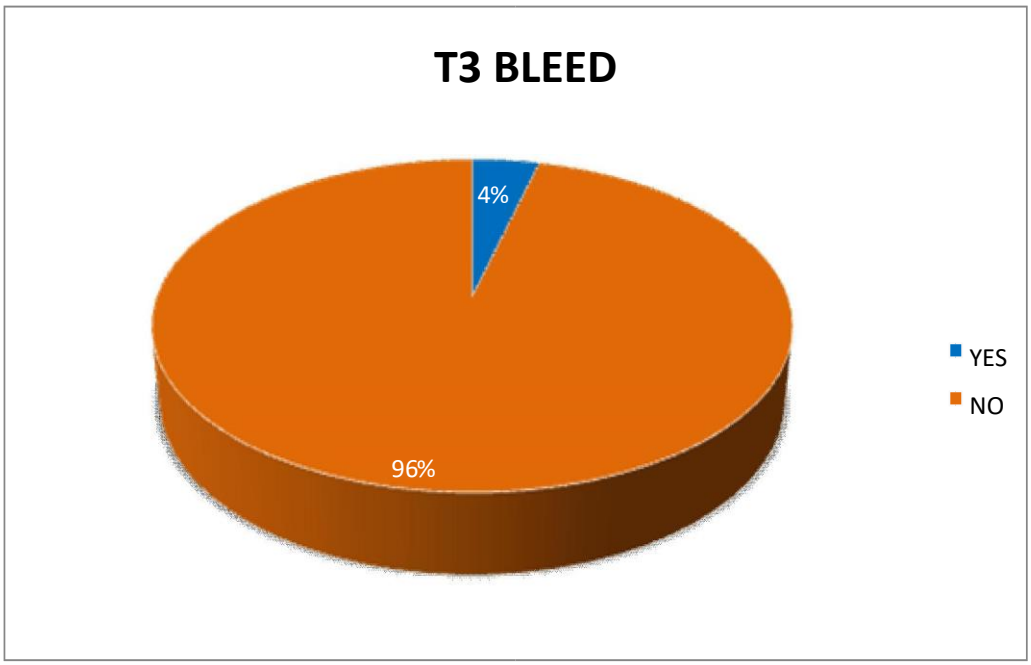


Figure no 9: Patients with the third trimester bleeding

ABRUPTION	**Frequency**	**Percent**
Yes	2	2.7
No	73	97.3
Total	75	100

Table 11: Distribution of patients with percent of abruption

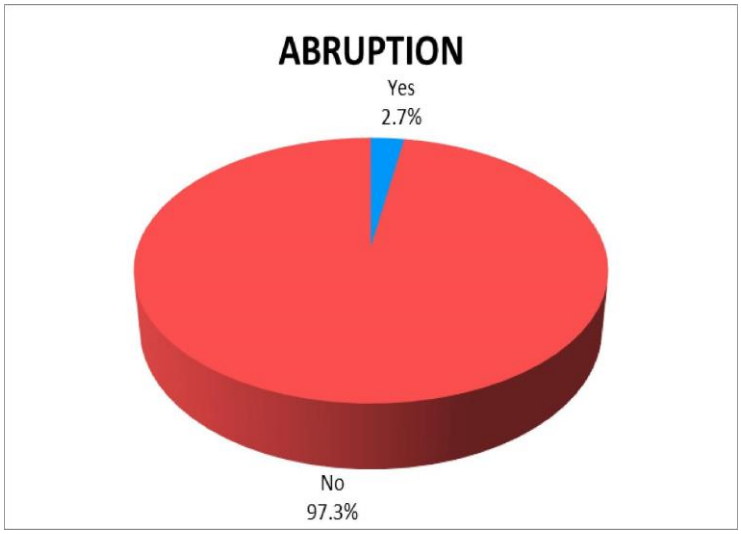


Figure 10: Patients with abruption

Out of the 75 patients who continued pregnancy only 2 (2.7%) had pre-eclampsia and IUGR.

Pre-eclampsia	Frequency	Percent
Yes	2	2.7
No	73	97.3
Total	75	100

Table 12: Distribution of patients who had pre-eclampsia

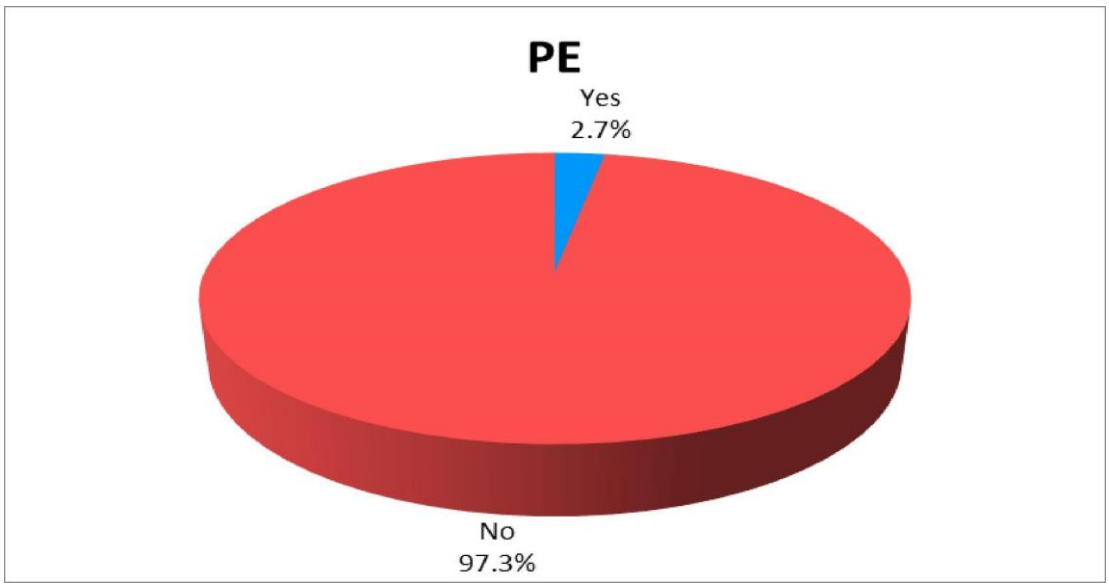


Figure 11: Patients with Pre-eclampsia

IUGR	Frequency	Percent
Yes	2	2.7
No	73	97.3
Total	75	100

Table 13: According to patients with IUGR

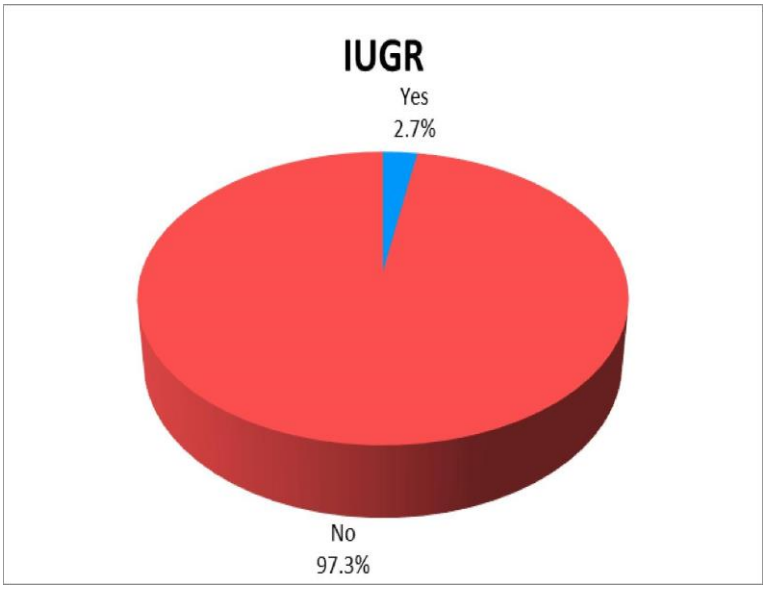


Figure 12: Patients with IUGR

Out of 75 patients, only 5 had PPROM (6.7%), and 7 with PROM(9.3%).

PPROM	Frequency	Percent
Yes	5	6.7
No	70	93.3
Total	75	100

Table 14: Distribution of patients who presented with PPROM

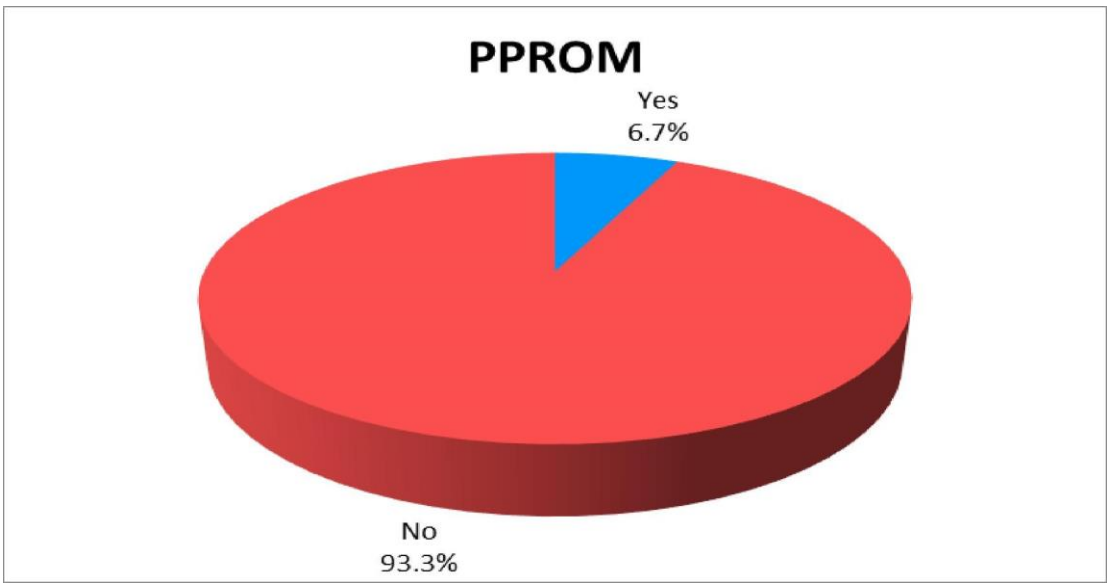


Figure no 13: Patients with PPROM

PROM	Frequency	Percent
Yes	7	9.3
No	68	90.7
Total	75	100

Table 15: Distribution of patients who presented with PROM

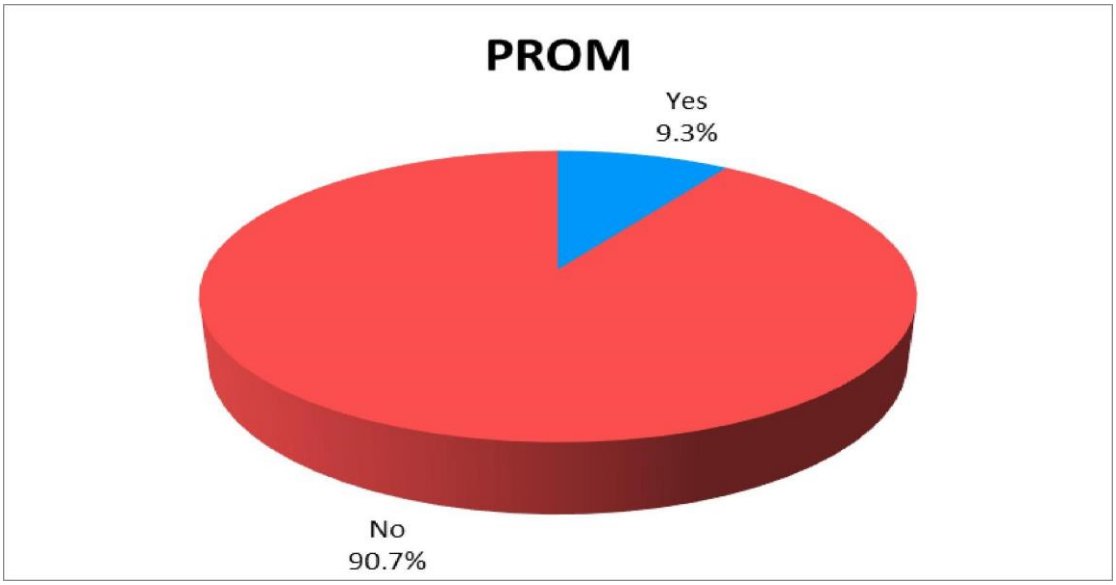


Figure no 14: Patients with PROM

Out of 75 patients, 62 (82.7%) had term deliveries, and 13 had preterm deliveries.

PRETERM/TERM	Frequency	Percent
Term	62	82.7
Preterm	13	17.3
Total	75	100

Table 16: Distribution of patients who delivered according to gestational age

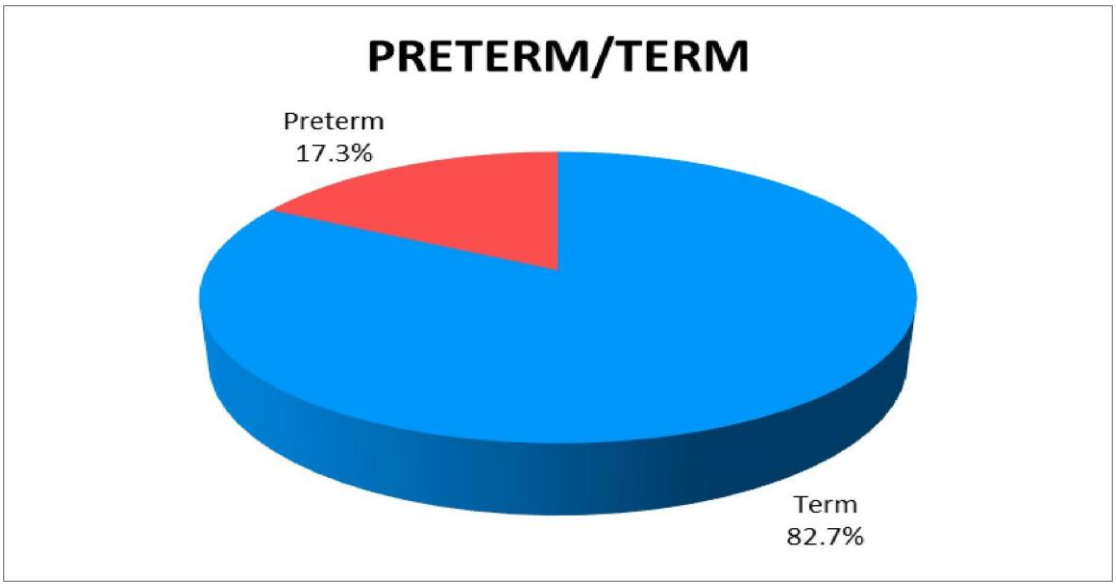


Figure no 15: According to gestational age at delivery

Out of the 75 patients, 13 had preterm deliveries, in that 1.3% (1) belonged to very early preterm, 5.3% early term & 10.7% belonged to late preterm.

GA		Frequency	Percentage
Term		62	82.7
Preterm	Very early	1	1.3
	Early	4	5.3
	Late	8	10.7
Total		75	100.0

Table 17: Distribution of patients according to the gestational age of delivery

Out of 75 patients 42 (56%) had FTND followed by LSCS for 27 (36%) PTVD for 6(8%)

Mode of delivery	Frequency	Percent
FTND	42	56
PTVD	6	8
LSCS	27	36
Total	75	100

Table 18: Distribution of patients according to the mode of delivery

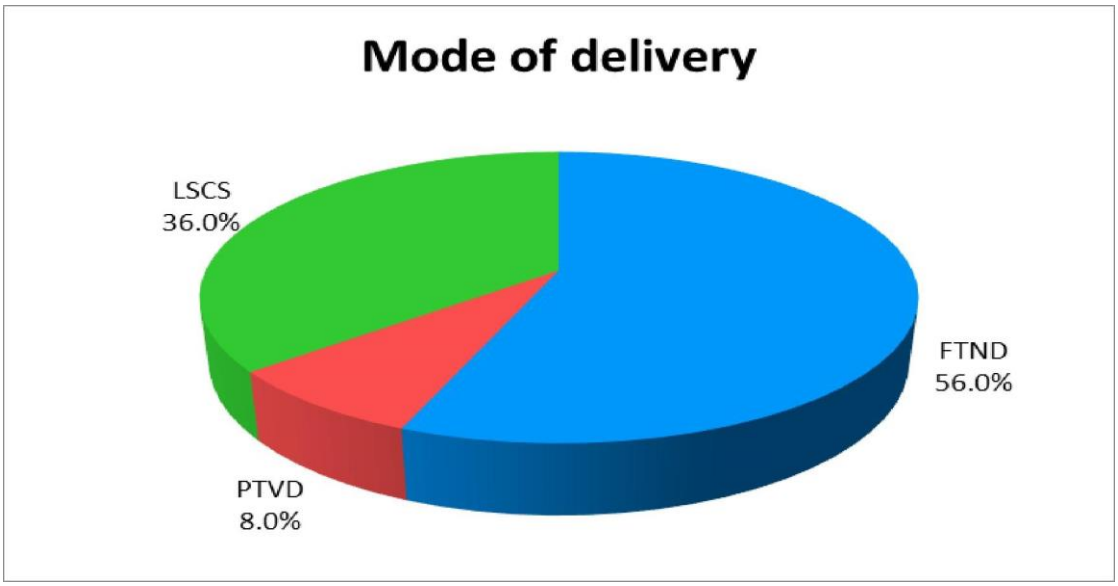


Figure no 16: Mode of delivery

APGAR	Frequency	Percent
1 ‘ 6 5’ 8	3	4
1’ 8 5’ 9	72	96
Total	75	100

Table 19: Distribution of babies with their APGAR scores

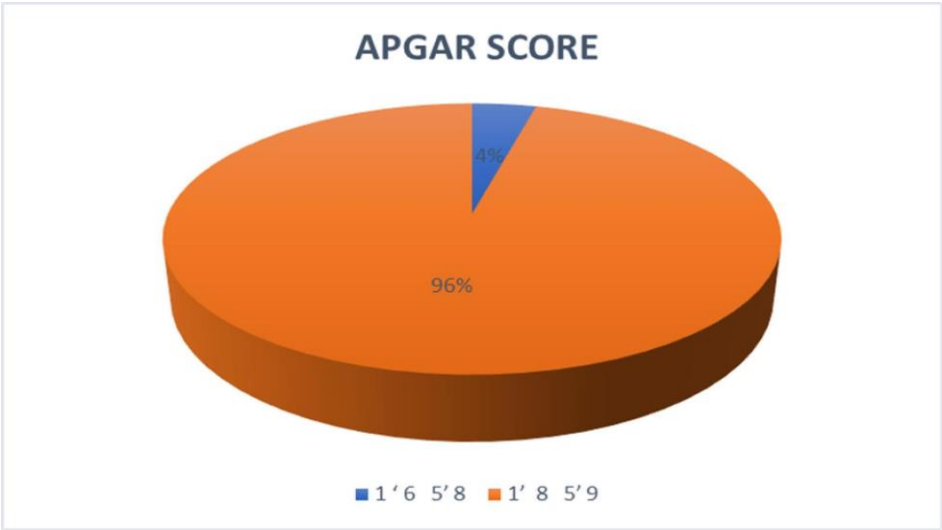


Figure 17: APGAR score

Out of the 75 patients majority of the babies belonged to birth weight > 3kg (49.3%), followed by 2.5 – 3kg (36%), 1.5- 2.5 kg (14.7%).

Birth weight	Frequency	Percent
1.5-2.5	11	14.7
2.5-3.0	27	36
>3	37	49.3
Total	75	100

Table 20: Distribution of babies according to the birth weights

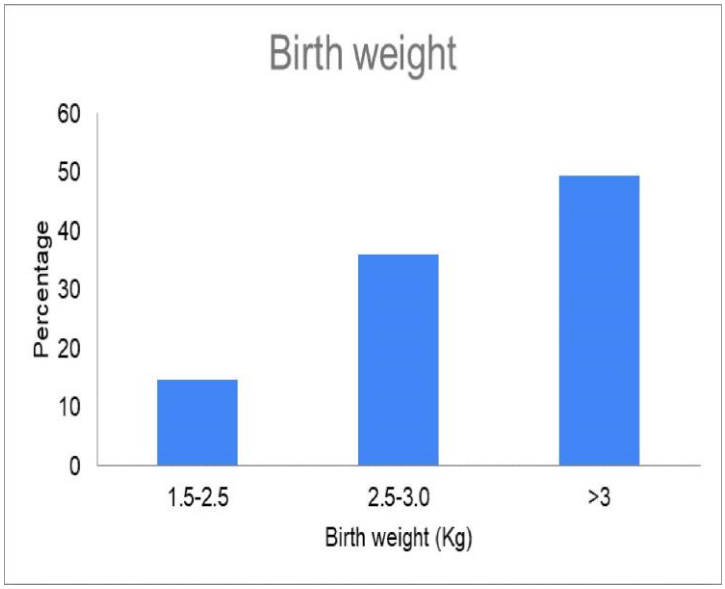


Figure 18: Distribution according to birth weight

Parity	SCH				Total		p
	Yes		No				
	N	%	N	%	n	%	
T2 BLEED	12	37.5	4	5.6	16	15.4	<0.001
T3 BLEED	1	3.1	2	3	3	3.1	0.980
Spontaneous	3	9.4	23	31.9	26	25	0.026
T2 Abortions	2	6.3	1	1.4	3	2.9	

Table 21: Association of sub chorionic bleed with abortion

Out of 16 patients with second-trimester bleeding, 12 had SCH which was statistically significant.
Out of 3 patients with third-trimester bleeding, 2 had no SCH, there was no statistical significance.
Out of a total of 29 abortions, 26 had first-trimester abortions, of which 23 didn't have SCH and it is not statistically significant.

OUTCOMES	SUBCHORIONIC HEMATOMA		P VALUE
	YES	NO	
PREECLAMPSIA (2)	1	1	0.681
IUGR (2)	1	1	0.681
PPROM (5)	1	4	0.85
PROM(7)	2	5	0.672
PRETERM DELIVERY (13)	5	8	0.408
MODE OF DELIVERY (LSCS): 27	13	14	0.103
LOW BIRTH WEIGHT (11)	4	7	0.15

Table 22: Association of sub-chorionic hematoma with maternal outcomes

IV. Discussion

All pregnant women, a total of 104 patients with first trimester vaginal bleeding presented to ER/OPD in the department of Obstetrics and Gynecology and their babies up to the neonatal period were followed up.

After taking a detailed history, physical and pelvic examination, and imaging techniques. Diagnosis and management are usually decided.

In our study, the mean age of the patients was 30 years, and the majority of the patients belonged to the age group of 26- 30 with percent of (39.4%), 31- 35 (37.5%), 36- 40 (9.6%), 18- 25 (13.5%). Similarly, in a study conducted by Bala N [51] mean age was 28.6 +/- 3 yrs, for Perera [52], the mean age was 28.8 +/- 9 yrs.

The mean BMI was 26 with the majority of patients belonging to a normal BMI of 18- 24.9 with a percent of 40.4 % (42) and overweight 38.5% (40).

The majority of the patients were primi with 60.6 % (63), similar study conducted by Kamble PD et al [7], primi constituted 63.9%.

61.5% (64) patients belonged to 6- 10 weeks, <6 weeks constituted 17.3% (18), > 10 weeks 21.2% (22), similar study by Bala N, [51] the majority of the population belonged to 8- 10 weeks with a percentage of 65.5%.

53.8% (56) patients presented with spotting PV followed by moderate bleeding at 35.6 % (37), then heavy which is 10.6% (11) compared to a similar study by Bala N [51], in which spotting constituted 61%, moderate bleeding at 29%, heavy 10%.

Out of the 104 study participants, 32 (30.8%) had SCH, and 72 (69.2%) did not have SCH.

Out of 104 study participants, 27.9% (29) had abortions, and 72.1 % (75) underwent delivery. In a similar study by Amirkhani [17] 70% ended up in delivery.

Out of the 75 patients delivered, FTND was 42 (56%), PTVD was 6 (8%) and LSCS 27 (36%). In a similar study by Patel NG [46] LSCS was 27 (36%).

Out of 104 study population, 16 (15.4%) had the second trimester bleeding, 3 (3.1%) had a third-trimester bleed

Out of 16 patients with second-trimester bleeding, 12 had SCH which was statistically significant (p value: <0.001). Out of 3 patients with third-trimester bleeds, only 1 had SCH, there was no statistical significance. Out of the total of 29 abortions, 26 had first-trimester abortions, of which 23 didn't have SCH and it is not statistically significant. Out of the 3 patients with second-trimester abortions, 2 had sub chorionic hematoma and there was a significant association (p value: 0.026) between SCH and second-trimester abortions.

Out of the total 75 patients who underwent delivery, only 2 had abruption with 2.7%, in a similar study by Kamble PD et al [7] abruption constituted 1.8%. In a similar study by Yakistiran [5], out of 400 patients, only one had an abruption.

Out of 75 patients who delivered, 2 (2.7%) had pre-eclampsia and 2 (2.7%) had IUGR, in a similar study by Bala N [51] preeclampsia was 2%. PPROM and PROM constituted 5 (6.7%) and 9.3 % respectively. In another study, by Sarmalkar MS [53] PROM was 11%.

Out of 75 patients who underwent delivery, 62 (82.7%) were term, and 13 (17.3%) were preterm.

In preterm, 1 (1.3%) very early, 4 (5.3%) early , 8 (10.7%) were late preterm

95.8% of babies had an APGAR score of 1': 8, 5' : 9.

Birth weight of babies, > 3kg babies constituted 49.3% followed by 2.5 – 3kg babies with 36% and 1.5 – 2.5 kg 14.7%.

V. Conclusion

It was concluded that in this study, pregnant patients who had a subchorionic hematoma in the first trimester had greater chances of bleeding in the second trimester and second trimester abortion with a significant p-value of <0.001 and <0.026 respectively.

Bleeding during the first trimester of naturally conceived pregnancies seems to occur without any clear physiological cause. Most pregnancies with early bleeding proceeded to normal delivery and healthy live birth. However, there was no significant relationship between them. In my study, there was no association found between the presence of sub chorionic hematoma and various maternal outcomes, such as miscarriages, PPROM/ PROM, preeclampsia, abruption, IUGR, mode of delivery and neonatal outcomes such as APGAR score and birth weight.

However, a large population or multicentric study is required to further evaluate the effect of early pregnancy bleeding on pregnancy outcomes in this environment.

Finally, in our study, we could conclude that subchorionic bleed itself is not a poor prognostic indicator in pregnancy with first trimester vaginal bleeding

One should make the choice of management, which can provide sensitive and complete care to women at this important time keeping in mind one goal: "Healthy mother and Healthy baby".

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