Obstetrics and Gynaecology Section

Evaluation of Pregnancy Outcome in Women with First Trimester Vaginal Bleeding: A Longitudinal Study at a Tertiary Care Hospital, Kolkata, India

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ABSTRACT

Introduction: First trimester vaginal bleeding, a serious obstetric challenge to developing embryo, occurs in 15-25% of all pregnant women. It is a matter of great concern to both mother and obstetrician for its increased association of adverse maternal and foetal outcome.

Aim: To measure the prevalence of patients with first trimester vaginal bleeding, to evaluate factors associated with it and to assess foeto-maternal outcome in those pregnant women.

Materials and Methods: This was a hospital-based, longitudinal study carried out among 120 women with first trimester vaginal bleeding having normal body weight, and regular cycles and agreeing to follow-up, at Department of Obstetrics and Gynaecology in a tertiary teaching hospital, Kolkata, West Bengal, India, from January 2019 to June 2020. The incidence of vaginal bleeding in first trimester, its risk factors, foeto-maternal outcome in terms of Pregnancy Induced Hypertension (PIH), abortions, preterm deliveries, Antepartum Haemorrhages (APH), birth weight of baby, low Appearance or colour of the baby, Pulse, Grimace, Activity, and Respiration (APGAR) score at birth was assessed. The descriptive statistics was used to calculate percentage and mean and Chi-square-test with significance value considered at p-value <0.05.

Results: Out of 4716 pregnant women attending in Obstetric clinic at their first trimester, 332 had vaginal bleeding, incidence being 7.04%. Out of 332 women, 120 study participants met inclusion criteria. Of 120 cases, 79 (65.8%) were from age group of 21-30 years. Highest incidence was 74 (61.7%) in primigravida. Incidence was high in poor socio-economic status (upper lower and lower) ie., 57 (47.5%) and unplanned cases, 87 (72.5%). On follow-up of 120 participants, 66 (55%) had threatened abortion, of them 51.5% (34/66) led to term pregnancy followed by preterm labour 39.4% (26/66) and only few, 9.09% (6/66) ended up with incomplete miscarriage. Spotting was most common nature of bleeding per vagina 41.7% (50/120). On follow-up of 60 (90.9%) viable pregnancies, PIH was in 12 (20%) cases and abruption was seen in one (1.6%). Majority of preterm babies 65.4% (17/26) needed Neonatal Intensive Care Unit (NICU) admission.

Conclusion: Vaginal bleeding in first trimester is an indicator of the maternal and foetal adverse consequences and results of this study can enrich our knowledge to plan and manage these pregnant women adequately.

Keywords: Antepartum haemorrhages, Foeto-maternal outcome, Pregnancy induced hypertension, Threatened abortion, Vaginal bleeding

INTRODUCTION

Vaginal bleeding before 12 weeks of gestation is relatively common obstetric event complicating nearly 20% of all pregnant women [1]. It creates a surge of maternal apprehension and emerging evidence suggests that it may be associated with poor foetal and maternal outcomes [2].

Bleeding per vagina in first trimester can be caused by several factors. Implantation bleeding, miscarriages (threatened, inevitable, incomplete and complete miscarriage), ectopic pregnancy and cervical pathology are the major factors besides molar pregnancy leading to first trimester vaginal bleeding [3,4]. Almost 50% of pregnancies with 1st trimester bleeding, come to an end with pregnancy loss [2]. Outcome of pregnancy often influenced by the gestational age at which bleeding occurs, causative factors and intensity of bleeding as well. If pregnancy continues poor maternal and foetal outcome such as preterm delivery, preeclampsia, abruption, foetal growth restriction may occur [2,3]. Maternal age, systematic diseases like diabetes mellitus, hypothyroidism, infertility treatment, thrombophilia, maternal weight and uterine structural anomalies reported to raise the chances of abortion. Although first trimester vaginal bleeding is a painful symptom, very little studies have been done scrupulously to explore the prevalence and predictors of bleeding. There is wide variations in estimates of prevalence of early pregnancy bleeding ranging from 7% to 24% have been reported in published literatures. Wide range in estimates is possibly due to variation in study design [5]. Comprehensive understanding about current pregnancy outcome following 1st trimester vaginal bleeding is very much pertinent not only to pregnant mothers but also to her attending obstetrician to plan adequate antenatal care and early intervention to reduce the maternal and perinatal complications. To evaluate adverse foetal outcomes following first trimester vaginal bleeding, several primary studies have been attempted, but a couple of them have remarked on adverse maternal outcome [6].

This study aimed to find out the prevalence, risk factors associated with first trimester vaginal bleeding and to evaluate foeto-maternal outcome in these pregnant mothers.

MATERIALS AND METHODS

This was a longitudinal, hospital-based observational study carried out at R.G. Kar Medical College and Hospital, a Government tertiary care teaching centre in Kolkata, West Bengal, India, amongst patients attended at Outpatient Department (OPD) and Emergency Unit in the Department of Obstetrics and Gynaecology over 18 months period from January 2019 to June 2020 after obtaining the Institutional Ethical Clearance through proper channel from the

Institutional Ethics and Review Committee (vide memo number RKC/515). Informed consent of the participants was obtained after proper counseling. For first nine months, from January 2019 to September 2019, authors enrolled the participants for the study and the next nine months i.e. from October 2019 to June 2020, authors followed-up them to evaluate the maternal and foetal outcome.

Inclusion criteria: Singleton pregnancy with first trimester vaginal bleeding attending the emergency and OPD, normal body weight, regular cycle, agreed to follow-up were included in the study.

Exclusion criteria: Women with chronic hypertension, uncorrected hypothyroidism, uncontrolled pregestational diabetes mellitus, known smoker, women on anticoagulant therapy, women with pre-existing cervical or uterine pathology, women with history of abortifacient intake, biochemical pregnancies were excluded from the study.

Sample size calculation: From the previous study, it has been found that incidence of first trimester bleeding is about 8.5% in the population [2]. Now using this formula:

$$z^2 \times p \times \frac{(1-P)}{d^2}$$

Here, z=1.96, p=0.085, d=0.05

Sample size was about 120. Authors further include 10% to account for dropout/missing data. So, a sample of 132 but 12 of them were lost to follow-up and So, a final sample of 120 was taken [Table/Fig-1].

[Table/Fig-1]: Depicting flowchart of participants enrolled in the study.
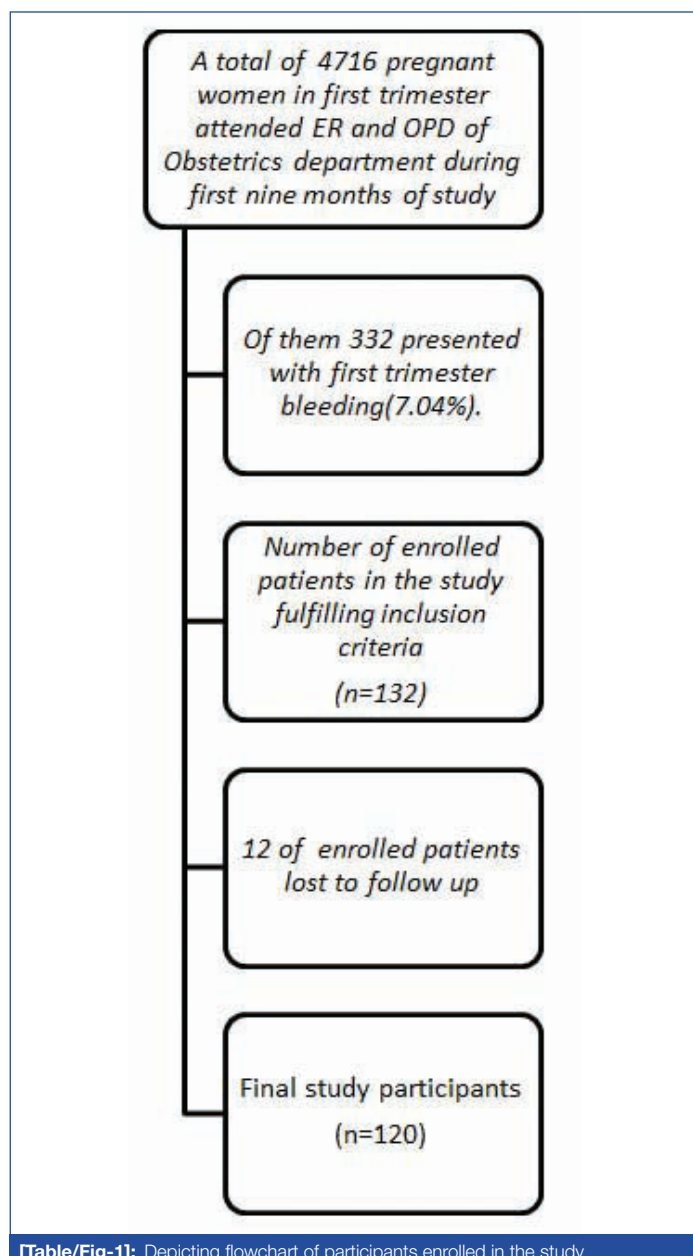
Procedure

Over the study period, following admission through OPD and emergency, every study participants was subjected to a routine physical, obstetrical and Ultrasonographic (USG) examination for confirmation of gestational age and diagnosis of foetal viability (threatened, inevitable, incomplete, complete abortions, molar or ectopic pregnancy). After confirmation of foetal viability, pregnant mothers were discharged with an advice to continue pregnancy and to attend antenatal care clinic regularly. They are followed-up till delivery or final outcome and the data regarding this were collected from records of antenatal cards and Bedhead Tickets (BHT) when they were admitted for child birth in future [Table/Fig-2]. All the findings and data regarding socio-demographic characteristics, detailed history, clinical presentation were noted. The class of socio-economic status of the patients was analysed on the basis of Modified Kuppuswamy scale and classified into lower middle, upper middle and low (upper lower and lower) socio-economic status [7].

[Table/Fig-2]: Depicting flowchart of study procedure.
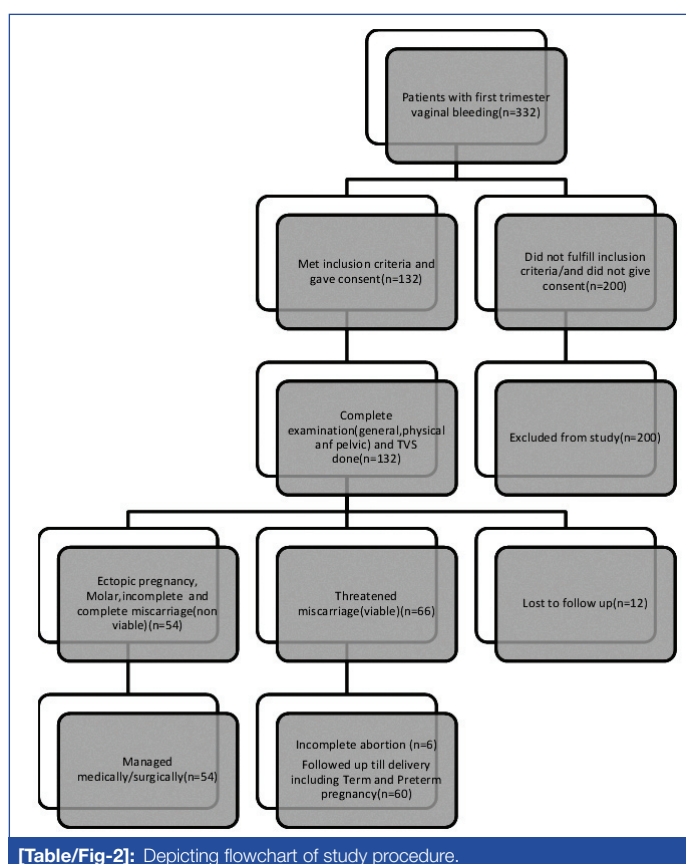
Nature of vaginal bleeding experienced in study period was recorded as 'spotting', 'more than spotting' and 'clot'. A spotting episode was noticed only while wiping, an episode having flow equivalent to usual menstrual period but lighter than heaviest day of flow of menstrual period was defined as more than spotting while an episode as heavy or heavier than usual menstrual period with passage of clots has been categorised under clots [8]. Laboratory investigations and ultrasound was collected and noted carefully. Any intervention or operative procedure required in course of management of the patient was also noted. Patients contact numbers and addresses were recorded for future correspondence.

Later the pregnancy outcome was evaluated in the form of obstetrical complications like placenta previa, abruption placentae, preterm labour, hypertensive disorder in pregnancy, and neonatal outcomes like prematurity, low birth weight, low Appearance, Pulse, Grimace, Activity and Respiration (APGAR) and Neonatal Intensive Care Unit (NICU) admission. Maternal data was collected from labour-room log book, antenatal records, patient BHTs and foetal

data were taken from neonatal record log books, nursery records and NICU register.

STATISTICAL ANALYSIS

Data was verified and entered in Microsoft Excel datasheet and all analysis was performed by using Microsoft 2010. Categorical data was represented by frequency and percentages of total cases by using descriptive statistics and Chi-square test was performed to measure the level of significance where p-value <0.05 was considered statistically significant.

RESULTS

Out of total 120 cases, majority of the cases 97 (80.8%) were admitted via Emergency Room (ER), belonged to upper lower class socio-economic status 47 (39.2%), in age group of 21-30 years 79 (65.8%) and booked cases 75 (62.5%). Mean age was 22.9±4 years and age range was 17-35 years. Most of them 104 (86.7%) had no history of infertility treatment and had unplanned conception 87 (72.5%) [Table/Fig-3].

Variables	Frequency (n=120)	Percentage (%)
Mode of admission		
Emergency	97	80.8
Outpatient Department	23	19.2
Socio-economic status (Revised Kuppuswamy scale updated for 2021) [7]		
Low Middle Class	43	35.8
Upper lower Class*	47	39.2
Lower Class†	10	8.3
Upper Middle Class	20	16.7
Age (years)		
≤20	34	28.3
21-30	79	65.8
≥31	7	5.8
Booking status		
Booked	75	62.5
Unbooked	45	37.5
History of infertility treatment		
No	104	86.7
Yes	16	13.3
Nature of conception		
Planned	33	27.5
Unplanned	87	72.5

[Table/Fig-3]: Socio-demographic variables in study participants.
*Upper lower and †lower class together=57(47.5%)

Most cases were primigravida 74 (61.7%), peak of incidence at gestational age of 6-10 weeks 76 (63.3%) and had spotting per vagina 50 (41.7%). Mean gestational age was 7 weeks 6 days±2 weeks 2 days (range=11 weeks 4 days to 4 weeks 3 days) [Table/Fig-4].

Threatened miscarriages found in 66 (55%) followed by incomplete abortion 41 (34.2%) were common pregnancy outcome in cases of first trimester vaginal bleeding. Spotting was the significant presentation in participants of threatened abortions. So there was definite association between nature of bleeding per vagina and diagnosis at first visit (Chi-square=84.644, p-value=0.001) [Table/Fig-5].

Amongst the threatened abortions (n=66), majority 60 (90.9%) progressed to viable pregnancies of which term pregnancy 34 (51.5%) followed by preterm labour 26 (39.4%) with spontaneous onset and only a few 6 (9.09%) ended with incomplete abortion as depicted in [Table/Fig-6].

Out of 26 preterm babies 17 (65.4%) needed NICU admission while only 7 (20.6%) term babies needed NICU admission. Most of

Obstetric variables	Frequency (n=120)	Percentage (%)
Parity		
0	84	70.0
1	27	22.5
2	07	5.8
3	02	1.7
Gravida		
1	74	61.7
2	32	26.7
3	10	8.3
4	3	2.5
5	1	0.8
History of bleeding in past pregnancy (Multigravida, n=46)		
No	29	63.4
Yes	17	36.6
Gestational age (weeks)		
<6	26	21.7
6-10	76	63.3
>10	18	15.0
Nature of bleeding per vagina*		
More than spotting	25	20.8
Clots	45	37.5
Spotting	50	41.7

[Table/Fig-4]: Distribution of obstetric factors.
*Criteria defined by Hassan W et al., [8]

Pregnancy outcome of vaginal bleeding at first trimester	Nature of bleeding per vagina			Total (n, %)
	More than spotting (n)	Clots (n)	Spotting (n)	
Complete miscarriage	3	0	2	5 (4.2%)
Ectopic pregnancy	0	0	5	5 (4.2%)
Incomplete miscarriage	3	37	1	41 (34.2%)
Molar pregnancy	2	0	1	3 (2.5%)
Threatened miscarriage	17	8	41	66 (55%)

[Table/Fig-5]: Aetiology of bleeding per vagina and its relation to nature of bleeding.
Chi-square=84.644, p-value=0.001; p-value <0.05 was considered statistically significant

Nature of per vaginal bleeding	Final outcome	n (%)
More than spotting (n=17)	Incomplete miscarriage	2 (11.8%)
	Preterm labour	11 (64.7%)
	Term pregnancy	4 (23.5%)
Clots (n=8)	Incomplete miscarriage	2 (25%)
	Preterm labour	5 (62.5%)
	Term pregnancy	1 (12.5%)
Spotting (n=41)	Incomplete miscarriage	2 (4.9%)
	Preterm labour	10 (24.4%)
	Term pregnancy	29 (70.7%)

[Table/Fig-6]: Depicting final outcome of threatened miscarriages on follow-up (n=66).
p-value <0.5 was considered statistically significant; (Chi-square statistic=17.2408; p-value=0.001735)

preterm babies (61.5%) and term babies (58.8%) had birth weight in the range of 2.5 to 2.9 kg. Of the preterm babies 26.9% had low birth weight and 11.5% were very low birth weight. It was also found that 38.5% preterm babies and 11.8% term babies had APGAR <7 at 1 minute [Table/Fig-7].

In this study, 16 (61.5%) of mothers who had preterm labour and 25 (73.5%) of those who delivered at term had no complication. But the result was not significant (p-value=0.663) as shown in

Parameters	Preterm (n, %)	Term (n, %)	Total (n)	χ^2; p-value
NICU admission				
No	9 (34.6%)	37 (79.4%)	46	χ^2=12.319 p-value=0.000448*
Yes	17 (65.4%)	7 (20.6%)	24	
Birth weight (kg) Mean±SD 2.645±0.580 kg				
Low birth weight (<2.5 kg)	7 (26.9%)	3 (8.8%)	10	χ^2=15.249 p-value=0.001616*
Very low birth weight (<1.5 kg)	3 (11.5%)	0	3	
2.5-2.9 kg	16 (61.5%)	20 (58.8%)	36	
>3 kg	0	11 (32.4%)	11	
APAGR score at 1 minute				
<7	10 (38.5%)	4 (11.8%)	14	χ^2=5.87 p-value=0.015401*
≥7	16 (61.5%)	30 (88.2%)	46	

[Table/Fig-7]: Outcome of newborn babies on follow-up of viable pregnancies preterm (n=26) and term (n=34).
*p-value <0.05 was considered statistically significant

[Table/Fig-8]. Regarding mode of delivery, both vaginal delivery and caesarean section rate was almost same (48.33% vs. 46.66%) as shown in [Table/Fig-9].

Complications	Preterm (n, %)	Term (n, %)
Abruptio placentae	0	1 (2.9%)
Hypertensive disorder of pregnancy	5 (19.2%)	4 (11.8%)
Hypertensive disorder of pregnancy and gestational diabetes mellitus (both)	2 (7.7%)	1 (2.9%)
Placenta praevia	3 (11.5%)	3 (8.8%)
No complications	16 (61.5%)	25 (73.5%)

[Table/Fig-8]: Maternal complications on follow-up of viable pregnancies preterm (n=26) and term (n=34).
Chi-square=2.39598; p-value=0.66335

Mode of delivery	n (%)
Vaginal delivery	29 (48.33%)
Instrumental delivery	3 (5%)
Caesarean section	28 (46.66%)

[Table/Fig-9]: Mode of delivery on follow-up of viable pregnancies (n=60).

DISCUSSION

Even though, the early pregnancy vaginal bleeding is potentially appalling symptom, the present published literatures are sparse to investigate its prevalence, patterns, and risk factors. Due to wide variations in the study design and methodology, the estimations of bleeding prevalence in first trimester recorded in different studies are imprecise and ranging from 7% to 24% [9-12]. This makes difficult to compare the study results.

The current study showed that prevalence of first trimester vaginal bleeding was 7.04%. The incidence recorded in several other studies is shown in [Table/Fig-10] [2,8,10,11,13-16].

In this study, 28.3% of participants had age <20 years, and highest incidence 65.8% was found in age of 21 to 30 years. Mean age in the study population was 22.9±4 years. Hasan R et al., observed in their study that highest incidence (45.9%) in age group 28-34 years [5]. Similar pattern of observation was reported by Kavyashree HS and Rajeshwari K, where incidence of first trimester vaginal bleeding was 70% in this age group [9]. Shivanagappa M et al., also noticed first trimester bleeding per vagina was very high (69%) in age group 21-30 years [17]. The study by Yasmin H et al., showed the mean maternal age was 26.53±6.36 years [18].

Author name	Incidence of early pregnancy bleeding
Kamble PD et al.,[2]	8.5%
Hassan W et al., [8]	37.84%
Yang J et al., [10]	24.4%
Axelsen SM et al.,[11]	16%
Harville EW et al.,[13]	9%
Zhong C et al.,[14]	21.4%
Smits LJM et al.,[15]	23%
Sun L et al.,[16]	24.2%
Present study	7.04%

[Table/Fig-10]: Incidence of vaginal bleeding in early pregnancy in published studies [2,8,10,11,13-16].

About 70% of study population was nulliparous (no previous viable pregnancy) and 74 (61.7%) women became first time pregnant, 22.5% had had a previous viable child birth, and 7.5% were multipara. Similar finding was reported in a study by Kamble PD et al., where 63.9% population was primigravida and 36.1% was multigravida [2]. In study by Amirkhani Z et al., 56.7% patients were primigravida, consistent with the current study [4]. But Kavyashree HS and Rajeshwari K, and Patel NG et al., found in their studies that multigravida were 60% and 66% respectively [9,19]. Manonmani and Nandini, showed in their study conducted on 150 patients that 58% were primigravida [20].

Present study showed, 21.7% had a gestational age of <6 weeks, and highest incidence 63.3% of vaginal bleeding was found in gestational age ranging from 6 weeks to 10 weeks. A study by Kamble PD et al., reported incidence of pregnancy failure 77% in those with less than 6 weeks gestation [2]. Shivanagappa M et al., had also observed the similar findings [17].

In the present study, it was found that 35.8% of population belonged to lower middle class, 47.5% were poor (belonging to upper lower and lower class) and 16.7% belonged to upper middle class. This finding is in concurrent with the study conducted by Zheng D et al., in China and Norsker FN et al., in Denmark which reported that lower socio-economic status was inversely proportional to spontaneous miscarriages [21,22].

Present study demonstrated that most frequent nature of bleeding was spotting 41.7% followed by clotting 37.5% and more than spotting 20.8%, which is comparable with study by Hasan R et al., where spotting was seen in 75.6% of subjects, light bleeding in 18.4% and 6.1% had heavy bleeding [5]. Threatened miscarriages, most common (55%) pregnancy outcome in our study, were significantly associated with spotting. Of 50 patients (41.7%) who had spotting, incidence of threatened miscarriages was very high 41 (82%) and of 45 women with passage of clots, 8 (17.7%) had threatened miscarriages. This is concurrent with study report of Kamble PD et al., which demonstrated that 83.2% had spotting with abortion rate of 81.2% while 16.8% had heavy bleeding with abortion rate 96.4% [2].

Most of the threatened abortions were continued as viable gestation either term or preterm. Present study demonstrated that those with more than spotting, had incomplete miscarriage in 11.8% on follow-up, 64.7% preterm labour, 23.5% had term pregnancy. Yakştiran B et al., reported 19.06% preterm delivery among patients with first trimester vaginal bleeding [3].

In those with passage of clots, 25% developed incomplete abortion on follow-up, 62.5% went through preterm labour, 12.5% proceeded to term pregnancy. Hasan R et al., reported 24% women with heavy bleeding experienced abortion [23].

In those with spotting, 4.9% developed incomplete miscarriage on follow-up, 24.4% progressed to preterm labour, 70.7% proceeded

to term pregnancy. In study by Verma SK et al., 61.7% of pregnancies with vaginal bleeding continued beyond 28 weeks and 19% had preterm birth [24]. Amirkhani Z et al., showed preterm labour in 25% of patients with history of first trimester bleeding [4]. Kanmaz AG et al., reported preterm labour in 6.2% patient [25].

Out of 60 viable pregnancies, 20% (n=12) women had pregnancy induced hypertension. The study conducted by Saraswat L et al., noted that incidence of PIH, preeclampsia or eclampsia was not significantly altered by bleeding in first trimester [26]. The incidence of PIH (20%) in the present study was also much higher in comparison to study by Kanmaz AG et al., which reported preeclampsia in 3.8% patients [25]. Incidence of abruptio placentae was found in 1 (2.9%) of the patients continuing pregnancy (n=60), in contrast to study of Amirkhani Z et al., which reported placenta abruption in 13.3% patients [4]. The present study resulted into low birth weight 26.9% among preterms and 20.6% NICU admission in term new born due to low birth weight and poor APGAR whereas in the study of Kanmaz AG et al., reported incidence of low birth weight 15.8% and 11% NICU admission [25].

A systematic review performed by Saraswat L et al., demonstrated that mode of delivery was not influenced by first trimester vaginal bleeding [26], which was in agreement to the present study findings i.e., same rate of both vaginal delivery and caesarean section.

The clinical implications of this study are close monitoring and focused attention to the mothers experiencing first trimester vaginal bleeding, so that the complications in ongoing pregnancy can be minimised by providing more serious prenatal surveillance and management to them to achieve successful pregnancy outcome. The strength of the present study was that it was a longitudinal study, where the pregnant women were enrolled very early in pregnancy and several maternal and foetal outcomes were studied methodically through regular antenatal check-ups, performed weekly which enabled us detection of adverse events at earliest and judicious intervention was taken.

Optimal counseling and appropriate prenatal care with follow-up, are advocated for the women of first trimester vaginal bleeding, especially with threatened miscarriage and those having bad obstetric history. It seems reasonable to study further to find optimal predictive factor for poor pregnancy outcome of these women.

Limitation(s)

Apart from small sample size, other limitations of this study are timing, severity, frequency, duration, and bleeding associated pain that seems to be effective factor in the end of pregnancy is not addressed here. The present study could not assess the association between threatened abortion congenital anomaly of the foetus. Long-term follow-up and prognostic evaluation also could not be done here.

CONCLUSION(S)

Pregnancy complicated by first trimester vaginal bleeding is highly associated with increased maternal and foetal morbidity. Majority of early pregnancy bleeding had threatened abortions with spotting, and were nulliparous, primigravida, gestational age 6-10 weeks and belonged to poor socio-economic status. So, there is a need of close monitoring and more vigilance for providing prenatal care more seriously to the pregnant mothers following threatened miscarriage to minimise the foeto-maternal complications.

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