

A Study of Outcomes in Pregnancies with First Trimester Bleeding**Gaurav Das¹, Arunav Sharma², Shruthi KS³, Mustajib Ali⁴**¹Department of Obstetrics and Gynaecology, 5 Air Force Hospital, Jorhat, Assam, India -785008²Department of Obstetrics and Gynaecology, 7 Air Force Hospital, Kanpur, Uttar Pradesh, India -208002³Department of Medicine, 5 Air Force Hospital, Jorhat, Assam, India -785008⁴Department of Radio Diagnosis, 5 Air Force Hospital, Jorhat, Assam, India -785008

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Corresponding Author: Dr Mustajib Ali

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Abstract**Background:** Threatened abortion during the first trimester of pregnancy can lead to complications that may adversely affect both maternal and perinatal outcomes. This study aims to understand the effect of threatened abortion in the current pregnancy on subsequent maternal and perinatal outcomes.**Methods:** A total of 150 patients with threatened abortion were assessed. Outcomes measured included the incidence of abortion, premature rupture of membranes (PROM), preterm labor, low birth weight (LBW) babies, fetal growth restriction (FGR), and maternal complications.**Results:** Of the 150 patients, 29 were lost to follow up. Of the remaining 121, 28 (21%) underwent abortions and 96 reached full term. The study found: The highest frequency of patients was in the age group of 28-32 years (38%). Most patients were multigravida (61%) compared to primigravida (39%). Preterm premature rupture of membranes (PPROM) was seen in 25% of mothers with first trimester bleeding, with 29% resulting in preterm babies. Pre-eclampsia was observed in 15% of mothers, and 33% underwent LSCS. Placental complications were noted in 11% of the cases, with placenta previa and accreta being the most common.**Conclusion:** While the type of bleeding appears to be a significant predictor for poor pregnancy outcomes, the gestational age at which it occurs doesn't seem to significantly impact the pregnancy's outcome. It is imperative to provide intensified prenatal care for pregnancies post-threatened miscarriage to optimize outcomes.**Keywords:** Threatened abortion, perinatal outcome, first trimester bleeding, preterm labor, fetal growth restriction.

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Introduction

Vaginal bleeding is a common first-trimester complication, often considered to be a sign of a problem in pregnancy [1]. It complicates 15-25% of all pregnancies [2]. It has been associated with adverse pregnancy outcomes. Approximately 50% of women who experience bleeding, will miscarry. Those who do not miscarry have increased risk of other complications associated with the pregnancy, including preterm delivery and low-birthweight infants [3]. Various meta-analyses indicate that vaginal bleeding is associated with a two times increased risk of other complications during that pregnancy [4]. It is also known that maternal age, systemic diseases such as diabetes mellitus, hypothyroidism, infertility treatment, thrombophilia, maternal weight and uterine structural anomalies increase the risk of imminent abortion [5]. Emerging evidence suggests that it may be associated with poor foetal and maternal outcomes. These risk rises with increased maternal age.

Understanding the nature of common biological processes, symptoms, and behavioural changes that occur during early pregnancy may contribute to increased knowledge of miscarriage risk factors [6]. The four major sources of non-traumatic bleeding in early pregnancy are miscarriage (threatened, inevitable, incomplete or complete), implantation of pregnancy, ectopic pregnancy, and cervical pathology [5]. Threatened miscarriage is diagnosed on the basis of documented fetal cardiac activity on ultrasound with a history of vaginal bleeding in the presence of a closed cervix [7]. It constitutes a source of anxiety for the mother, family as well as the care providers. If after a positive pregnancy test, vaginal bleeding occurs, it requires further assessment in order to identify normal or abnormal development of the pregnancy or a pathologic condition that requires intervention [8]. In the majority of cases of threatened miscarriage, the bleeding is of unknown origin and usually slight.

It is hypothesized that first trimester bleeding may indicate an underlying placental dysfunction, which may manifest later in pregnancy causing adverse outcomes such as increased risk of pre-eclampsia syndrome, preterm delivery, prelabour rupture of membranes (PROM), and FGR²³. The purpose of this observational study was to investigate the effect of first-trimester vaginal bleeding on maternal and perinatal outcomes in a group of patients who presented to the OPD of a tertiary care hospital, with complaints of bleeding per vaginum in their 1st trimester of pregnancy. They were evaluated and followed up throughout their pregnancy for the outcome in mother and foetus. The results will help in understanding better the outcomes of pregnancies complicated by first trimester vaginal bleeding and also guide us in follow-up and monitoring of these patients to improve and prevent adverse outcomes.

Aim

To find out the effect of threatened miscarriage on pregnancy outcome.

Objectives of the Study: To study various maternal and fetal complications in pregnancies affected by first-trimester bleeding.

Primary Outcomes

Obstetrical complications: Abortions, Preterm labour, PROM.

Fetal complications: Low birth weight baby, Preterm baby, FGR

Secondary Outcomes: Pre-eclampsia, Stillbirth, Abruption Placenta.

Methods and Material

This prospective observational study was carried out on women with singleton pregnancies who presented to Out Patient Department of a tertiary care hospital with complaints of vaginal bleeding before 14 weeks period of gestation from Nov 2018 to May 2020. As per sample size calculation, 150 patients with a history of amenorrhea and urine pregnancy test positive with bleeding per vaginum in the first trimester (< 14 weeks) were enrolled in the study. The Inclusion criteria were (a) Pregnancies with Weeks of amenorrhea of <14weeks, (b) Positive pregnancy confirmed by USG or UPT, (c) Bleeding per vaginum, (d) Patients willing to participate in study and (e) Single on pregnancies. Patients with the following criteria were excluded from the study: (a) History of intake of abortifacients, (b) Ectopic pregnancy, (c) Molar pregnancy, (d) Patients with chronic hypertension, (e) Any local lesion and bleeding disorders (f) Patients with More Than 14 Completed Weeks of Gestation and (g) Patients unwilling to participate in study. The sample size was calculated based on incidence and prevalence of first trimester

vaginal bleeding in pregnancy in previous studies. Considering standard error variate (Z) as 1.96 at 95% confidence level, sample size of 150 was deemed to be adequate for this study. A detailed obstetrical and medical history was taken. A structured proforma was prepared. Detailed history was taken regarding the age of pregnancy at the time of bleeding, and amount of bleeding. Ultrasound for fetal viability and placental localization was done. Patients with spotting or light bleeding were followed on OPD basis. Patients with heavy bleeding were admitted in hospital. They were followed up in the ANC OPD and outcomes were noted as per the study variables. During the course of study, 29 women were lost to follow up. Thus, leaving 121 eligible women for this study.

Patients with threatened miscarriage were managed with adequate rest till 48 hrs of cessation of bleeding, folic acid supplementation and progesterone was given.

Descriptive and inferential statistics were used to analyze the data. All the data that was derived from the study were analysed by using Microsoft Excel and IBM SPSS Version 22.0. Chi-Square and Fischer's tests were performed to find out significant association between various categorical parameters. Independent t test and Mann-Whitney U tests were used to calculate significant difference between the parameters. P value <0.05 was considered statistically significant.

Results

A total of 150 pregnant women in the age group of 20 to 40 years with bleeding per vaginum in first trimester attending OPD or inpatients in the department of obstetrics and gynaecology, in a tertiary care hospital in Bangalore were enrolled in this observational study. Out of these, 29 were lost to follow up and rest were followed up for various outcomes. We found that, out of these 121 women, 25 had abortions. The observations made at the culmination of the study are as follows.

The mean age of the mother was 27.7±4.3 years, the range being 18 to 38 years. Most patients were in the age group of 28-32 years (38%) followed by 23-27 years (37%) and 21-25 years (16.50%). 12% mothers belonged to the age group 18-22 years and another 12% belonged to age group 33-38 years. (Table 1)

In our study we found that 73(61%) were multigravida and 47(39%) were primigravida. (Table 1 and Fig 4). The mean gestational age at bleeding was 9 Weeks 3 Days ± 2 Week 1 Day. A majority of mothers had bleeding between 8-10 weeks period of gestation (44%) followed by patient who had bleeding at <8 weeks period of gestation (33%) and 10- 14 weeks (23%). (Table 1)

Table 1: Demographic Data

SNo.	Parameter	Observedvalue
1.	Age(Years)mean±SD	27.7±4.3
2.	Maternalagegroups,n (%)	
	18-22years	15(12%)
	23-27years	45(37%)
	28-32years	46(38%)
	33-38years	15(12%)
3.	Parity, n(%)	
	Primi	47(39%)
	Multi	73(61%)
4.	Mean Gestational Age, mean±SD	9Weeks3Days±2Week1Day
5.	Gestational Ageat bleeding	
	<8weeks	40(33%)
	8-10weeks	53(44%)
	10-14weeks	28(23%)
6.	Typeof Bleeding	
	Bleeding	27(22%)
	Spotting	94(78%)

In our study we found that a majority (78%) of patients presented with spotting followed by 22% who had bleeding (Table 1). Maternal outcomes included abortions, PROM, PPRM, pre term deliveries, low birth weight babies and preeclampsia / gestational hypertension.

Out of 121 mothers in our study, 25(21%) mothers underwent abortions and 79% had live births. (Table 2). In our study we found that only 28 mothers

(29%) delivered preterm. (Table 2). Rest delivered at term. Out of these 28 mothers, 16(53%) had PPRM. (Table 2). Out of 68(71%) mothers who delivered at term, only 8 (12%) had PROM. (Fig10). In our study, out of the 96 mothers who delivered, 16 % developed Pre- eclampsia. (Table 2). In our study we found that, out of 96 mothers 34(35%) were delivered by LSCS and 62(65%) mothers delivered vaginally.

Table 2: Maternal Outcomes

S No.	Parameter	Observed value
1.	Abortions, n(%)	
	No	96(79%)
	Yes	25(21%)
2.	Preterm, n(%)	28(29%)
	PPROM(n=28)	16(53%)
3.	Term, n(%)	68(71%)
	PROM(n=68)	8(12%)
4.	Pre Eclampsia	
	No	81(84%)
	Yes	15(16%)
5.	Mode of Delivery	
6.	LSCS	34(35%)
	Vaginal	62(65%)

Table 3: Foetal Outcomes

S. No.	Parameter	Observed value	P-value
1.	LBW (<2.5 Kg)		
	No	56(58%)	0.0270
	Yes	40(42%)	
2.	Preterm Babies		
	Yes	28(29%)	0.0001
	No	68(71%)	
3.	FGR (<10 th Centile)		
	No	67(70%)	0.0001
	Yes	29(30%)	
4.	Birth weight, mean±S D	2.6±0.5	

Out of 96 live births 44(42%) were LBW babies.(Table3). The mean birth weight of 96 babies was 2.6±0.5kg. Out of 96 mothers who delivered with first trimester vaginal bleeding, we found a significant association between first-trimester vaginal bleeding and low birth weight babies. Around 42% babies, who delivered were low birthweight. Our study showed that around 30% of mothers

with first-trimester vaginal bleeding had FGR.

In our study, only 16% mothers who had first trimester vaginal bleeding developed preeclampsia. (Table 2). Placental complications (APH) was present in 11% deliveries. Complications included Placenta Previa, accreta, abruptio and manual removal of placenta. (Table 5).

Table 4: Relationship between type of bleeding and maternal outcome

Outcome		Bleeding N(%)	Spotting N(%)	P Value
Abortions	No	8(30%)	88(94%)	0.0001
	Yes	19(70%)	6(6%)	
Term/Preterm	Preterm	1(13%)	27(31%)	0.4305
	Term	7(88%)	61(69%)	
LBW	No	6(75%)	46(52%)	0.4976
	Yes	2(25%)	42(48%)	
Preeclampsia	No	7(78%)	73(84%)	0.6473
	Yes	2(22%)	14(16%)	
Mode of Delivery	LSCS	3(38%)	31(35%)	1
	Vaginal	5(63%)	57(65%)	

Most abortions 19(70%) were seen in mothers with bleeding compared to spotting 6(6%). A significant association was found between type of bleeding and abortions, as P<0.05. Proportion of preterm babies 7(88%) was higher in mothers with bleeding compared to mothers with spotting 61(69%). However, no significant association was found between type of bleeding and term or preterm delivery as p value>0.05. Number of LBW babies were higher in mother with spotting 42(48%) compared to mothers with bleeding 2(25%). There was no significant association between type of bleeding and LBW babies. Preeclampsia was observed more in mothers with bleeding 2(22%) compared to mothers with spotting 14 (16%). But here also, no significant association was found between type of bleeding and preeclampsia. Mode of delivery

was almost equally distributed between mothers with bleeding and mothers with spotting, showing no statistical significance. We also analysed an additional variable that is gestational age at bleeding with respect to the type of bleeding. Out of 121 mothers 27(22%) had bleeding and 94(78%) had spotting. In my study, bleeding was most commonly seen in 14(35%) mothers of gestational age <8 weeks and least (9%) seen in mothers of gestational age 8-10 weeks. Most spotting 48(91%) was observed in mothers with bleeding at 8-10 weeks and least 26(65%) at <8 weeks.(Refer table 5 and Fig 16). A significant association was observed between type of bleeding and gestational age of bleeding, as P= 0.021. Hence in my study mothers having first trimester vaginal bleeding was common before 8 weeks period of gestation.

Table 5: Distribution of Type of Bleeding with respect to the gestation alage at bleeding

Type of bleeding	<8Weeks		8-10 Weeks		10-14Weeks		Total		P
	N	%	N	%	N	%	N	%	
Bleeding	14	35%	5	9%	8	29%	27	22%	0.02
Spotting	26	65%	48	91%	20	71%	94	78%	
Grand Total	40	100%	53	100%	28	100%	121	100%	

Table 6: Placental Complications

S. No.	Parameter	Observed value
1.	Placental Complication (APH)	
	Absent	85(89%)
	Present-	11(11%)
	a)Previa	4
	b)Accreta	2
	c)Abruptio	1
	d)Manual Removal	2
	e)PPH	2

Out of 96 mothers, placental complications were observed in 11(11%) mothers, out of which 4 devel-

oped placenta previa, 2 developed placenta accreta, 1 had abruptio placenta, 2 had manual removal

and 2 had PPH. In our study we found out that all the babies who were delivered had normal APGAR. All the babies who delivered were liveborn and there was no still birth in our study.

Discussion

The present study was conducted with an aim to find out effect of threatened abortion in the current pregnancy on the subsequent maternal and perinatal outcome. Out of the 150 patients studied, 29 were lost to follow up. Out of the remaining 121 patients, 28 aborted and 96 were followed up till delivery. The incidence of abortion, PROM, preterm labour in our study was 21%, 12% and 29% respectively. We noted 42 % of LBW babies and 30% FGR babies. Many studies from India and western countries have reported similar outcomes and pregnancy complications of 1st trimester vaginal bleeding.

In our study, most patients were in the age group of 28-32 years (38%) followed by 23-27 years (37%) and 21-25 years (16.50%). The age wise distribution of cases is similar to studies by Manonmani et al [9], Dwivedi S et al [10], Kamble PD et al [11] and Amirkhani et al [17]. However Kalyani Singh and Preeti Lewis et al [12] found first-trimester vaginal bleeding at a younger age group of 20-30 years in their respective studies. The mean age in our study was 27.7±4.3years. This is in accordance with the study of Perera BH et al [13].

In our study, 61% of the mothers were multigravida and 39% were primigravida. These results are very similar to a study of first-trimester vaginal bleeding outcomes conducted by Patel NG et al [14], Patel S et al [15], and Hasan R et al [16]. It is different from the studies of Manonmani et al [9], Kamble PD et al [11] and Amirkhani et al [17] who found that majority of women with first trimester vaginal bleeding were primigravida; however, the difference was statistically not significant.

In our study 21% mothers underwent abortions and 79% mothers continued with pregnancy which is similar to studies by Amir Khani et al [17] and Agrawal et al [18]. However this is in contrast to the study by Kamble et al [11] where 84% patients aborted and 16% patients continued pregnancy.

In our study 70% abortions (19 mothers) were seen in patients with bleeding compared to spotting (6%). A significant association was observed between type of bleeding and gestational age of bleeding. First trimester abortions were common in mothers who had first trimester vaginal bleeding before 8 weeks period of gestation. It is very similar to study by Shivanagappa M et al [19], who noticed that 35% cases had vaginal bleeding between 6-8 weeks. However, this result was not in congruence to the study done by Amirkhani et al [17] and Kamble et al [11].

Our study found that the rewash significant association between the bleeding severity pattern and outcome of pregnancy. Out of 121 mothers 27(22%) had bleeding and 94(78%) had spotting. Most spotting 48(91%) was observed in mothers with bleeding at 8-10 weeks and least 26(65%) at <8 weeks. In a study by Agrawal et al [18], incidence of spontaneous abortion, PROM, preterm and low birthweight were more common in patients with 1st trimester bleed than 2nd trimester and in heavy bleeders than light bleeders within cases. Similarly, Weiss et al [20], and Chung et al [21], have reported that the risk of fetal loss was directly proportional to the amount of vaginal bleeding but they found an increased risk of preeclampsia after light bleeding, but not after heavy bleeding.

Preterm delivery is the leading cause of death of normal newborns [22]. Preterm premature rupture of membranes (PPROM) occurs in up to 40% of preterm deliveries [13]. In our study, it was found that PPRM occurred in 25% out of 96 mothers who had first trimester vaginal bleeding. It was also found that most PPRM happened in mothers who had bleeding in 1st trimester at 8-10 weeks of gestational age i.e. around 31%. However, this association was not significant. In a study by Agrawal et al [18], it was seen that, women who have bleeding in the early pregnancy are at significantly increased risk of PROM preterm labour.

Out of 96 babies, 28(29%) were preterm babies. This is in agreement with the previous studies [6, 23]. In our study most preterm babies 11(37%) were born to mothers of <8 weeks gestational age of bleeding. However, studies by Strobino et al. failed to show an association between preterm delivery and threatened abortion [24].

Mean Birth weight is dependent on gestation, ethnicity, maternal weight and height. Our study also tried to find the association between first trimester vaginal bleeding and birth weight of babies. The mean birthweight of 96 babies was 2.6±0.5 kg. Out of 96 mothers 30% had FGR. Most FGRs 23 (51%) were seen in mothers of 8-10 weeks of gestational age at bleeding and least 7(33%) seen in mothers of 10-14 weeks of gestational age at bleeding. Agarwal et al (2013) reported mean Birth weight to be 2.47 ± 0.69 kg, in 49 babies of mothers with first trimester bleeding [18]. The difference in mean birthweight seemed to be related to premature delivery.

In our study all (100%) babies had 5 min APGAR of more than 7. Findings are similar to the study by Wijesiriwardana et al where they found no significant differences in the Apgar scores at 5 minutes in the case-control study [29].

Pre-eclampsia was present in 15 (16%) mothers out of 96 mothers. However, our study did not find any

significant association between pre-eclampsia and gestational age at bleeding. In a large prospective study by Smits et al, the risk of pre-eclampsia was similar for women with and without an episode of vaginal bleeding at ≤ 20 weeks of gestation was 5.5% vs. 5.3%, respectively. Bleeding during the first trimester was not significantly associated with pre-eclampsia [25].

Out of 96 mothers 33% delivered by LSCS for obstetric indications only. Rest delivered vaginally. Our study didn't find any strong association between first trimester vaginal bleeding and mode of delivery. Saraswat et al. performed a systematic-review and demonstrated that first trimester bleeding has no effect on route of delivery [26]. However, some other studies have shown that possibility of caesarean section in women with bleeding is more than others. In the study by Amirkhani et al. 38% patients had vaginal delivery whereas 41% had to undergo a LSCS. [17]

S Agrawal et al [18] found no statistically significant difference in the mode of delivery between those who had first trimester bleeding and those who had not. In contrast Sipila et al reported a higher caesarean section rate in the cases with bleeding [27]. The variability of results obtained in different studies seemed to be due to lack of consistencies observed between these studies, in the definition of the upper limits of abortion used, size of the study population, gestational age at presentation and to a lesser extent the statistical test used.

In our study among the 121 patients, 21% ended with first trimester miscarriage, 2% second trimester miscarriage, 21% preterm and 79% full term birth.

In our study, we found that 11% (eleven) of the patients under study developed placental complications; out of which a majority had placental previa and accreta. A small percentage (2%) of the patients had manual removal of placenta and PPH.

In the current study we observed that there is no significant difference in the incidence of preeclampsia, abruption placentae, and placenta Previa. Our data shows that the incidence of these complications was relatively increased, but not at significant levels as compared to normal incidence which is matching with previous studies. [2,28].

Conclusion

From our study it can be concluded that the bleeding in the first trimester was more common in multi-gravida. It was more common in the age group of 26 to 30 years. It was common between 9 to 12 weeks of gestation. Abortions were significantly increased in the mothers who had bleeding versus is mothers who had spotting only in their first trimester. The results also showed that even though type of bleeding is strongly associated with out-

come of pregnancy, the gestational age at which it occurs is not statistically linked to the outcome of pregnancy. In our study we also found that first trimester vaginal bleeding had a significant effect on the outcome of birth weight of babies as there was increased incidence of low birth weight babies and FGR. The maternal outcomes like PPROM, pre-eclampsia, APH, was not significantly increased in the patients with first trimester vaginal bleeding. However, considering the results of present study, first trimester bleeding can be a predicting factor in terms of mother and infant consequences of pregnancy and it is necessary to increase the knowledge of pregnant women in this regard for closer care.

There is a need to monitor patients after a threatened miscarriage to minimise these complications, and such pregnancies demand more intensive prenatal care. The identification of these high risk groups should enable better management protocols and new therapeutic protocols to improve neonatal outcome. With regard to the different studies, it seems reasonable to study further to find the best predictor for poor pregnancy outcome in women with threatened miscarriage. Investigations that determine the diagnostic and prognostic parameters are of value and more careful surveillance should be performed for them.

Declarations:

Sponsor: Self

Ethical Clearance: Approved by IEC, CHAFB

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