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Original Research Article

Pregnancy outcome in women with first trimester vaginal bleeding: a prospective cohort study

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ABSTRACT

Background: 15 –25% of all pregnant women experience first trimester vaginal bleeding, a major obstetric hazard to the growing embryo. This study aimed to study the maternal and fetal outcome in women with first trimester vaginal bleeding.
Methods: This was a prospective study conducted in Department of Obstetrics and Gynecology, Credence Hospital, Thiruvananthapuram, Kerala over a period of 18 months. All women with singleton pregnancy with first trimester vaginal bleeding, were included and compared with group without history of first trimester vaginal bleeding during the same period. A detailed history was taken, the characteristics of all the patients and outcome of mother and baby were noted and data was collected through self-administered pretested structured questionnaire.
Results: It showed that study variables such as age, socio-economic status, BMI, obstetric score, chronic hypertension, hypothyroidism were found to have no statistically significant association with vaginal bleeding. Mode of conception, H/O bleeding in previous pregnancies, pre gestational diabetes were statistically significant. Variables such as GDM, PROM, FGR, preterm delivery, mode of delivery, gestational age were examined as statistically significant risk factors of first trimester vaginal bleeding. Incidence of miscarriage, gestational diabetes, PPROM, FGR, Preterm delivery, Low birth weight, Low APGAR score and NICU admissions were higher in subjects with first trimester bleeding when compared to comparative group.
Conclusions: Such high-risk cases need utmost care and well-equipped medical center so that risk can be reduced or prevented.

Keywords: First trimester, Vaginal bleeding, Risk factors, Miscarriage, Prospective cohort study, Relative risk

INTRODUCTION

Giving birth is a major turning point in a marriage and a life-altering experience. The fetus and placenta provide the signals that induce most of the pregnancy-related changes. Pregnancy loss prior to 20 weeks of gestation is termed "miscarriage." Threatened miscarriage typically transpires during the first trimester and is more commonly linked with vaginal bleeding and uterine cramping in a viable pregnancy prior to 20 weeks of gestation. A definitive diagnosis of threatened miscarriage is made by ultrasonographic examination, confirming the presence of fetal heart activity in an intrauterine pregnancy.[1] Approximately 25% of women encounter early-stage hemorrhage, associated with the risk of miscarriage. Progesterone supplementation did not decrease the

incidence of miscarriages in women with first-trimester bleeding, as indicated by the randomized Progesterone in Spontaneous Miscarriage (PRISM) study.[2] Understanding the outcomes of pregnancies that experience first trimester bleeding is pertinent for both women and their obstetricians to effectively plan antenatal care and contemplate clinical interventions during pregnancy. Age of first pregnancy is on the rise in Kerala and rates of couples seeking infertility is also increasing. Hence this study is aimed to evaluate maternal and fetal outcome in first trimester vaginal bleeding.

METHODS

This was a prospective single center cohort study conducted in Department of Obstetrics and Gynecology, Credence Hospital, Thiruvananthapuram, Kerala over a period of 18 months (May 1 2023 to November 1 2024), to study the maternal and fetal outcome in women with first trimester vaginal bleeding. All women with singleton pregnancy with first trimester vaginal bleeding (13weeks+6 days), who attended the gynec OPD were included. A comparative group without history of first trimester vaginal bleeding was taken during the same period. A detailed history was taken for all these patients and a complete general, physical and obstetrical examination performed at each visit. The characteristics of all the patients related to their age, gravidity, gestational age, duration and amount of bleeding, duration of hospital stay, treatment modalities and outcome of mother and baby were noted and data was collected through self-administered pretested structured questionnaire. The patients were followed up prospectively in antenatal clinics and those with threatened miscarriage were managed conservatively as per the protocol. Subjects with multiple pregnancy, ectopic pregnancy, those with history of trauma in current pregnancy, known thrombophilia or hematological disorders/ on anticoagulant and those who are not giving consent were excluded from this study.

Complications like, miscarriage, preterm premature rupture of membranes (PPROM), premature rupture of membrane (PROM), Placenta previa, Abruptio placenta, preterm deliveries FGR, Mode of delivery, low birth weight, APGAR score and NICU admissions of babies are noted. The study has begun after obtaining clearance from the Institutional Ethical Committee and scientific committee dated on 20 April 2023.

Based on the results of reference- Suganya M, out of 200 cases with threatened miscarriage 32 cases had preterm delivery among and that is around 16.0% as compared with 9.0% in the control group and the minimum sample size required for the study was 145 per group.[3] Statistical analysis was done using IBM SPSS version 20.00 (Chicago USA). The quantitative data was represented as mean±SD and qualitative data as number and percentage. To test the statistical significance of the association of all categorical variables with presence/absence of vaginal bleeding, Pearson Chi-square test/Fishers exact test was applied and relative risk was calculated for outcome measures. A p value of <0.05 was considered to be statistically significant.

RESULTS

Table 1 showed that study parameters such as pre gestational diabetes, mode of conception and history of first trimester vaginal bleeding were found to be statistically significant.

Table 1: Comparison of study variables with 1st trimester vaginal bleeding.

Variables	1st trimester vaginal bleeding		P value
	Present (%)	Absent (%)	
Age group (years)			
20-30	89 (61.4)	81 (55.9)	0.636
31-35	38 (26.2)	42 (29)	
>35	18 (12.4)	22 (15.2)	
Socio economic status			
Upper	9 (6.2)	9 (6.2)	0.577
Upper middle	105 (72.4)	112 (77.2)	
Middle	31 (21.4)	24 (16.6)	
BMI			
Underweight (<18.5)	1 (0.7)	5 (3.4)	0.256
Normal weight (18.5-22.9)	58 (40)	58 (40)	
Overweight (23-24.9)	53 (36.6)	43 (29.7)	
Obese (>= 25)	33 (22.8)	39 (26.9)	
Obstetric score			
PRIMI para	76 (52.4)	91 (62.8)	0.075
Multi para	69 (47.6)	54 (37.2)	
H/O 1st trimester bleeding in previous pregnancy			
Yes	52 (35.9)	28 (19.3)	0.002*
No	93 (64.1)	117 (80.7)	

Continued.

Variables	1st trimester vaginal bleeding		P value
	Present (%)	Absent (%)	
Mode of conception			
Natural	112 (77.2)	125 (86.2)	0.04
ART	33 (22.8)	20 (13.8)	
Pre gestational diabetes			
Yes	6 (4.1)	0 (0)	0.039*
No	139 (95.9)	145 (100)	
Chronic hypertension			
Yes	4 (2.8)	2 (1.4)	0.680
No	141 (97.2)	143 (98.6)	
Hypothyroidism			
Yes	48 (33.1)	59 (40.7)	0.181
No	97 (66.9)	86 (59.3)	

*p value <0.05 considered as statistically significant.

Table 2: Association of maternal and fetal outcomes with 1st trimester vaginal bleeding.

Variables (risk category)	1st trimester vaginal bleeding		RR (95% CI)	P value
	Present (%)	Absent (%)		
Gestational diabetes	38 (29.2)	23 (15.9)	1.843 (1.163-2.921)	0.008*
Gestational hypertension	23 (17.7)	22 (15.2)	1.166 (0.683-1.990)	0.573
Placenta previa	2 (1.5)	1 (0.7)	2.23 (0.205-24.315)	0.924
PPROM (yes)	16 (12.3)	2 (1.4)	8.923 (2.091-38.070)	<0.001*
PROM	12(9.2)	13(9)	1.037(0.487-2.175)	0.939
FGR	22 (16.9)	7 (4.8)	3.505 (1.549-7.935)	0.001*
Preterm delivery	40 (30.8)	13 (9)	3.432 (1.923-6.125)	<0.001*
Mode of delivery				0.005*
LSCS	92 (70.76)	79 (54.48)	1.29 (1.079-1.563)	
Gestational age of confinement (weeks)				<0.001*
<37	40 (30.8)	13 (9)	3.43 (1.923-6.125)	
Birth weight				<0.001*
Low birth weight (<2.5 kg)	29 (22.30)	18 (12.41)	1.76 (1.050-3.080)	
APGAR score				<0.001*
≤6	19 (14.61)	3 (2.06)	7.06 (2.139-23.32)	
NICU admission	28 (21.53)	8 (5.51)	3.90 (1.845-8.258)	<0.001*

*p value <0.05 considered as statistically significant.

Other parameters had no statistically significant association with first trimester vaginal bleeding. The table 2 demonstrated that maternal outcomes such as gestational diabetes, PPROM, FGR, preterm delivery, LSCS, gestational age less than 37 weeks were statistically higher in women with 1st trimester vaginal bleeding.

Fetal outcomes such as low birth weight, APGAR score, NICU admission were also showed higher rate in women with 1st trimester vaginal bleeding.

DISCUSSION

We studied 145 subjects with first trimester vaginal bleeding as case group and 145 women without first trimester vaginal bleeding as comparative group. No significant difference in maternal age (p=0.636) has been observed in this study. The variation of age distribution with other study findings were because of various age gradings followed in the different studies, and the variance in the sample size. In this study, majority of the subjects belonged to the upper middle class in the cases group (72.4%) and comparative group (77.2%). But Nashkar et al reported that incidence of first trimester bleeding was high in poor socio-economic status (upper lower and lower) that is 47.5%.[4] No statistically significant difference in BMI was observed between the two groups and the p value was 0.256 similar to Kanmaz et al (p=0.441) Arora et al reported similar incidence of primipara and multipara among case group(50.9% and 49.1%).[5,6] In our study 35.9% of subjects in the study group and 19.3% of subjects in the comparative group had history of 1st trimester bleeding in the previous pregnancy. There was statistically significant difference with a p value of 0.002. Of the study population, 22.8% of subjects in case group and 13.8% of subjects in comparative group conceived by ART and 77.2% of subjects in cases and 86.2% of subjects in comparative group conceived naturally, which was similar to the study by Vashisth in

which 28.4% had assisted conception whereas 71.6% had spontaneous conception .[7]

Similar to our study Lykke et al reported that First-trimester bleeding in the first pregnancy increased the risk of recurrence in the second pregnancy from 2.2% to 8.2% (OR=4.05;95% CI3.78-4.34).[8] There was statistically significant (p=0.039) difference between cases and comparative group regarding pre gestational diabetes. In the study by Kanmaz et al reported incidence of 8.6% among case group and 5.5% in the comparative group.[5] There was no statistically significant (p=0.680) association between cases and comparative group regarding chronic hypertension, hypothyroidism.

Incidence of gestational diabetes was lesser in the studies by Dharamdasani, and Patil (12.8%), Arora et al (8%) and Kanmaz et al (8.6%,5,5%) than ours.[9,6,5] There was no statistically significant difference (p=0.573) between cases and comparative group regarding incidence of gestational hypertension, similar to the study by Gupta V et al (p=0.643).[10] Incidence of placenta previa among case group in our study was similar to the studies by Vashisth (1.2%), Dharamdasani, and Patil (1.1%).[7-9] Incidence of PPROM in our case group was similar to Siddu et al (11.32%) but study by Bala et al (2.68%), and Vashisth (1.2%) reported less incidence than ours in case group.[11,12,7] Almost similar incidence noted among both the groups in our study but Dadkhah et al reported more incidence in case group (10.2%) than in comparative group (4.8%).[13] Our study showed incidence of FGR among case group was more than the comparison group, similar to the studies by Gupta et al (12.7% and 1.4%). Risk of preterm delivery was 3.5 times higher among case group in our study i.e., RR of 3.432 (CI 1.923-6.125) and was significant (p=<0.001).[10] Hossain et al reported that any vaginal bleeding in early pregnancy was associated with a 1.57-fold increased risk of preterm delivery (95%CI:1.16-2.11).[14]

Almost similar rate of vaginal delivery and caesarean section among case group reported by Umeshchandra S, and Patil LD study (32% and 35%)) and Agarwal A, and Dewan PJ study, (38.8% and 41.1%).[15,16] 30.8% of subjects in case group and 9% of subjects in comparative group were delivered < 37 weeks in our study and 69.2% of subjects in case group and 91% of subjects in comparative group delivered ≥37 weeks.

Incidence of low-birth-weight babies in our study was comparable to studies by Gupta et al (21.1%) and (18.3%) and Ayub et al (28.33% and 11.66%).[10-17] 14.61% babies in case group and 2.06% babies in comparative group had low (≤6) APGAR score, 7 times risk in developing low APGAR among babies born in case group. In our study, 21.53% of babies in case group and 5.51% of babies in comparative group needed NICU admission. There was 3.9 times risk for NICU admission with RR of 3.90(CI;1.845-8.258) among babies of case group that was statistically significant (p<0.001). That means more numbers of cases in the cases group needed admission, similar to the studies by Kanmaz et al (11% and 8.4%).[5]

First trimester vaginal bleeding is significantly associated with various adverse pregnancy and neonatal outcome. Incidence of miscarriage, gestational diabetes, PPROM, FGR, preterm delivery, low birth weight, low APGAR score and NICU admissions were higher in subjects with first trimester bleeding when compared to the comparative group. Such high-risk cases need utmost care and well-equipped medical center so that risk can be reduced or prevented.

Strengths

This was a prospective study and there was no attrition.

Limitations

This was a prospective study conducted in a multispecialty hospital in an urban setting. The sample size was calculated based on only one primary outcome, namely preterm labour. The severity of vaginal bleeding was assessed based on the patient's subjective description.

CONCLUSION

First trimester vaginal bleeding is significantly associated with various adverse pregnancy and neonatal outcome. Incidence of miscarriage, gestational diabetes, PPROM, FGR, Preterm delivery, Low birth weight, Low APGAR score and NICU admissions were higher in subjects with first trimester bleeding when compared to the comparative group. Such high-risk cases need utmost care and well-equipped medical center so that risk can be reduced or prevented.

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