

Evaluation of Prothrombin Time, International Normalized Ratio and Platelet Counts among Women Presenting with First-Trimester Vaginal Bleeding: A Prospective Analytical Cross-Sectional Study.

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Abstract

Background:

First-trimester vaginal bleeding is a common obstetric emergency associated with adverse pregnancy outcomes. Assessment of coagulation parameters may help identify women requiring closer clinical monitoring.

Aim:

To evaluate prothrombin time (PT), international normalized ratio (INR), and platelet count among women presenting with first-trimester vaginal bleeding and determine their association with bleeding severity and clinical diagnosis.

Materials and Methods:

This prospective hospital-based analytical cross-sectional study was conducted at Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, over 12 months. A total of 180 pregnant women aged 18–40 years with singleton pregnancies, gestational age ≤ 13 weeks, and first-trimester vaginal bleeding were enrolled. Clinical evaluation, ultrasonography, complete blood count, platelet count, PT, and INR were performed. Data were analysed using SPSS version 26, with appropriate statistical tests; $P < 0.05$ was considered statistically significant.

Results:

The mean age was 26.8 ± 4.5 years, with 41.1% of participants aged 25–30 years. Threatened abortion was the most common diagnosis (54.4%), followed by incomplete abortion (17.8%). Mean PT increased progressively from 12.7 ± 0.8 seconds in threatened abortion to 16.5 ± 1.6 seconds in inevitable abortion ($P < 0.001$). Mean INR increased significantly with bleeding severity, from 1.02 ± 0.09 in mild bleeding to 1.28 ± 0.17 in severe bleeding ($P < 0.001$), while platelet count declined from 2.42 ± 0.47 lakh/mm³ to 1.61 ± 0.36 lakh/mm³ ($P < 0.001$). Abnormal PT, INR, and platelet counts were observed in 19.4%, 16.1%, and 14.4% of participants, respectively. Pregnancy continued in 56.7% of women during follow-up.

Conclusion:

First-trimester vaginal bleeding was associated with significant alterations in PT, INR, and platelet count, particularly with increasing bleeding severity. Coagulation assessment may aid early identification of women requiring closer monitoring.

Recommendation:

PT, INR, and platelet count assessment should be considered alongside clinical evaluation and ultrasonography, particularly in moderate-to-severe bleeding. Further multicentre studies are warranted to validate these findings.

Keywords: First-trimester vaginal bleeding; Prothrombin time; International normalized ratio; Platelet count; Coagulation profile; Threatened abortion; Pregnancy complications.

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INTRODUCTION

Vaginal bleeding during the first trimester is one of the most common obstetric emergencies, affecting approximately 20–25% of clinically recognized pregnancies. Although nearly half of these pregnancies ultimately result in a live birth, first-trimester bleeding remains an important clinical concern because it is associated with an increased risk of spontaneous abortion, ectopic pregnancy, hydatidiform mole, preterm birth, and other adverse maternal and fetal outcomes (1–4).

Pregnancy is characterized by physiological changes in the coagulation system that produce a hypercoagulable state, an adaptive mechanism intended to minimize excessive blood loss during delivery. These changes include increased plasma concentrations of coagulation factors VII, VIII, X, and fibrinogen, together with reduced fibrinolytic activity. While these physiological adaptations help maintain haemostasis during pregnancy, significant vaginal bleeding in early gestation may disturb this balance, resulting in measurable alterations in coagulation parameters. Therefore, timely assessment of coagulation status may assist clinicians in identifying women at increased risk of haemorrhagic complications and adverse pregnancy outcomes (1,5–7).

Prothrombin time (PT) is a routinely performed laboratory investigation that evaluates the integrity of the extrinsic and common coagulation pathways by measuring the activity of coagulation factors II, V, VII, X, and fibrinogen. The International Normalized Ratio (INR) standardizes PT values across different laboratories, allowing reliable assessment and comparison of coagulation status. Platelets play a crucial role in primary haemostasis by facilitating platelet plug formation at sites of vascular injury. A reduction in platelet count may impair clot formation, prolong bleeding, and contribute to adverse obstetric outcomes (12–15).

Previous studies have reported significant alterations in coagulation parameters among women presenting with first-trimester vaginal bleeding. Prolonged PT, elevated INR, and reduced platelet counts have been associated with increased bleeding severity and pregnancy loss. Knez et al. demonstrated that coagulation abnormalities were more pronounced in women experiencing severe first-trimester bleeding, highlighting the importance of early laboratory evaluation (5). Similarly, Singh et al. reported significantly prolonged PT and INR, along with lower platelet counts, among women with incomplete abortion accompanied by severe vaginal bleeding compared with those diagnosed with threatened abortion (11).

Current clinical practice guidelines issued by the American College of Obstetricians and Gynecologists (ACOG) and the

Royal College of Obstetricians and Gynaecologists (RCOG) recommend comprehensive clinical assessment, including history, physical examination, and ultrasonography, for women presenting with early pregnancy bleeding. However, laboratory evaluation of coagulation parameters may provide valuable complementary information, particularly in women with moderate-to-severe haemorrhage or recurrent bleeding episodes, thereby facilitating early recognition of coagulation abnormalities and appropriate clinical management (8–10).

Despite the clinical importance of coagulation assessment, prospective data evaluating PT, INR, and platelet count among women with first-trimester vaginal bleeding remain limited in eastern India. Generating regional evidence is important because patient demographics, healthcare access, and disease patterns may vary across different populations. Therefore, the present prospective hospital-based analytical cross-sectional study was undertaken to evaluate coagulation parameters in women presenting with first-trimester vaginal bleeding at a tertiary care teaching hospital and to determine their association with the severity of bleeding and clinical diagnosis.

MATERIALS AND METHODS

Study Design

This was a prospective hospital-based analytical cross-sectional study conducted to evaluate coagulation parameters among pregnant women presenting with first-trimester vaginal bleeding.

Study Setting

The study was conducted jointly in the Department of Obstetrics and Gynaecology and Department of Pathology, Shri Krishna Medical College and Hospital (SKMCH), Muzaffarpur, Bihar, India, a tertiary care teaching hospital that provides comprehensive obstetric and emergency maternal healthcare services.

Study Duration

The study was conducted over a period of 12 months. The study was conducted from 1 August 2024 to 31 July 2025.

Study Population

The study included pregnant women presenting to the Department of Obstetrics and Gynaecology with vaginal bleeding during the first trimester of pregnancy who fulfilled the eligibility criteria.

Sample Size

The sample size was calculated using the single-proportion formula, where n represents the required sample size, $Z_{\alpha/2}$ is 1.96 for a 95% confidence level, p is the anticipated proportion (50%), and d is the allowable absolute precision (7.3%). Substituting these values into the formula, $n = (1.96)^2 \times 0.50 \times 0.50 / (0.073)^2 = 180.4$. Accordingly, the required sample size was approximately 180 participants. Therefore, 180 eligible pregnant women presenting with first-trimester vaginal bleeding were consecutively enrolled during the 12-month study period.

Eligibility Criteria

Inclusion Criteria

- Pregnant women aged 18–40 years
- Singleton pregnancy
- Gestational age ≤ 13 weeks
- Clinically confirmed vaginal bleeding during the first trimester
- Willingness to provide written informed consent

Exclusion Criteria

- Known inherited or acquired coagulation disorders
- Chronic liver disease
- Current anticoagulant therapy
- Chronic thrombocytopenia
- Multiple pregnancy
- Autoimmune disorders
- Severe systemic illness affecting coagulation

Study Procedure

After obtaining written informed consent, all eligible participants underwent a comprehensive clinical evaluation. The following information was recorded using a predesigned case record form:

- Demographic characteristics (age and gravidity)
- Detailed obstetric and medical history
- Gestational age at presentation
- Clinical assessment of vaginal bleeding (mild, moderate, or severe)
- General and systemic examination
- Obstetric examination
- Ultrasonographic evaluation to establish the diagnosis and assess fetal viability

Laboratory Investigations

Venous blood samples were collected under aseptic precautions at the time of presentation before initiation of definitive treatment.

The following investigations were performed:

- Complete blood count (CBC)

- Platelet count
- Prothrombin Time (PT)
- International Normalized Ratio (INR)

Laboratory investigations were performed in the central clinical laboratory of the institution following standard operating procedures and routine quality-control measures.

Outcome Measures

Primary Outcome

- Assessment of coagulation parameters (PT, INR, and platelet count) among women presenting with first-trimester vaginal bleeding.

Secondary Outcomes

- Association between PT and clinical diagnosis.
- Association between INR and severity of vaginal bleeding.
- Association between platelet count and severity of vaginal bleeding.
- Frequency of abnormal coagulation parameters.
- Pregnancy outcome during follow-up (continuation of pregnancy, spontaneous abortion, or surgical evacuation).

Statistical Analysis

Data were analysed using IBM SPSS Statistics version 26.0. Continuous variables were expressed as mean $\pm$ standard deviation, and categorical variables as frequencies and percentages. Differences in continuous variables between multiple groups were assessed using one-way analysis of variance (ANOVA), while categorical variables were analysed using the Chi-square test. A two-tailed P -value < 0.05 was considered statistically significant.

Bias

Potential sources of bias were minimized by using predefined eligibility criteria, consecutive enrolment of eligible participants, standardized clinical assessment, and laboratory investigations performed at presentation using institutional standard operating procedures and routine quality-control measures. Participants with known coagulation disorders, chronic liver disease, anticoagulant therapy, chronic thrombocytopenia, multiple pregnancy, autoimmune disorders, or severe systemic illness affecting coagulation were excluded.

Ethical Considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and the Indian Council of Medical Research (ICMR) National

Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017).

Ethical approval was obtained from the Institutional Ethics Committee of Shri Krishna Medical College and Hospital, Muzaffarpur, before commencement of the study.

Written informed consent was obtained from all participants prior to enrolment. Participation in the study was entirely

voluntary, and participants had the right to withdraw from the study at any stage without affecting their routine medical care. All patient information was kept confidential by assigning unique identification numbers and de-identifying personal information before analysis.

RESULTS

Table 1. Demographic Characteristics of the Study Participants (n = 180)

Age Group (years)	Frequency (n)	Percentage (%)
18–24	66	36.7
25–30	74	41.1
31–35	31	17.2
>35	9	5.0
Mean age (years)	26.8 ± 4.5	—

The study included 180 pregnant women presenting with first-trimester vaginal bleeding. The majority of participants belonged to the 25–30-year age group (41.1%), followed by the 18–24-year group (36.7%). Women aged >35 years constituted only 5.0% of the study population. The mean age of the participants was 26.8 ± 4.5 years, indicating that first-trimester vaginal bleeding was most frequently observed during the peak reproductive age.

Table 2. Distribution According to Gravidity

Gravidity	Frequency (n)	Percentage (%)
Primigravida	82	45.6
Multigravida	98	54.4

Multigravida women comprised 54.4% of the study population, while 45.6% were primigravida, indicating a slight predominance of multigravid women among those presenting with first-trimester vaginal bleeding.

Table 3. Distribution According to Gestational Age

Gestational Age	Frequency (n)	Percentage (%)
5–7 weeks	56	31.1
8–10 weeks	82	45.6
11–13 weeks	42	23.3

Most women (45.6%) presented between 8 and 10 weeks of gestation, followed by 31.1% presenting between 5 and 7 weeks. Approximately one-quarter (23.3%) presented between 11 and 13 weeks of gestation.

Table 4. Clinical Diagnosis

Diagnosis	Frequency (n)	Percentage (%)
Threatened abortion	98	54.4
Incomplete abortion	32	17.8
Missed abortion	25	13.9
Inevitable abortion	15	8.3
Complete abortion	10	5.6

Threatened abortion was the most common clinical diagnosis, accounting for 54.4% of cases. Incomplete abortion (17.8%) and missed abortion (13.9%) were the next most frequent diagnoses, whereas complete abortion constituted the smallest proportion (5.6%).

Table 5. Severity of Vaginal Bleeding

Severity	Frequency (n)	Percentage (%)
Mild	96	53.3
Moderate	58	32.2
Severe	26	14.5

More than half of the women (53.3%) presented with mild vaginal bleeding, while approximately one-third (32.2%) had moderate bleeding. Severe bleeding was observed in 14.5% of participants.

Table 6. Mean Prothrombin Time According to Clinical Diagnosis

Diagnosis	Mean PT (seconds)
Threatened abortion	12.7 ± 0.8
Missed abortion	13.5 ± 0.9
Complete abortion	14.2 ± 1.0
Incomplete abortion	15.8 ± 1.4
Inevitable abortion	16.5 ± 1.6

One-way ANOVA: $F = 49.86$, $P < 0.001$

Mean PT increased progressively across the diagnostic categories, from 12.7 ± 0.8 seconds in women with threatened abortion to 16.5 ± 1.6 seconds in those with inevitable abortion. The differences among the diagnostic groups were statistically significant ($P < 0.001$).

Table 7. Mean INR According to Severity of Vaginal Bleeding

Severity	Mean INR
Mild	1.02 ± 0.09
Moderate	1.12 ± 0.13
Severe	1.28 ± 0.17

One-way ANOVA: $F = 36.72$, $P < 0.001$

The mean INR increased with increasing severity of vaginal bleeding, from 1.02 ± 0.09 among women with mild bleeding to 1.28 ± 0.17 among those with severe bleeding. The differences were statistically significant ($P < 0.001$).

Table 8. Mean Platelet Count According to Severity of Vaginal Bleeding

Severity	Platelet Count (lakh/mm ³)
Mild	2.42 ± 0.47
Moderate	2.05 ± 0.43
Severe	1.61 ± 0.36

One-way ANOVA: $F = 31.94$, $P < 0.001$

Mean platelet count showed a progressive decline with increasing severity of bleeding. Women with severe bleeding had the lowest mean platelet count (1.61 ± 0.36 lakh/mm³), whereas those with mild bleeding had the highest mean platelet count (2.42 ± 0.47 lakh/mm³). The differences were statistically significant ($P < 0.001$).

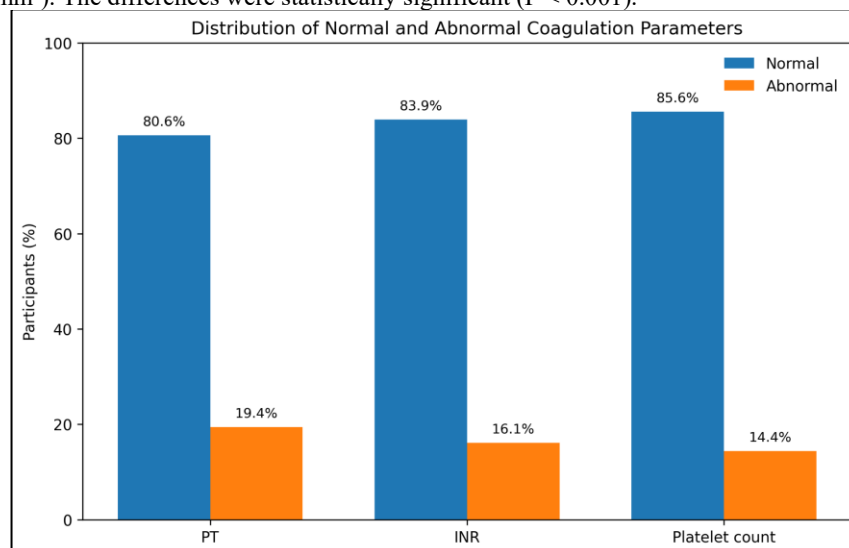


Figure 1. Distribution of normal and abnormal PT, INR, and platelet counts among study participants. Abnormal PT was observed in 19.4% of participants, followed by abnormal INR in 16.1% and reduced platelet count in 14.4%. Prolonged PT was the most frequently observed coagulation abnormality in the study population.

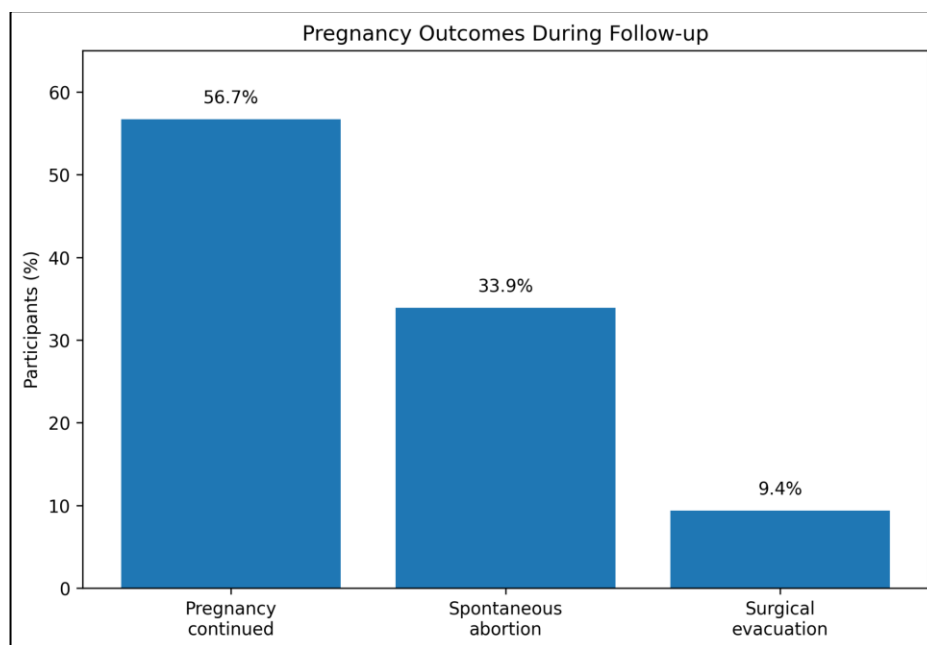


Figure 2. Distribution of pregnancy outcomes during follow-up, showing continued pregnancy, spontaneous abortion, and surgical evacuation. During follow-up, 56.7% of pregnancies continued, while 33.9% resulted in spontaneous abortion. Surgical evacuation was required in 9.4% of cases.

DISCUSSION

The present prospective hospital-based analytical cross-sectional study evaluated coagulation parameters among women presenting with first-trimester vaginal bleeding and assessed their association with the severity of bleeding and clinical diagnosis. The findings demonstrated significant alterations in prothrombin time (PT), International Normalized Ratio (INR), and platelet count, particularly among women with more severe clinical presentations and greater bleeding severity.

The majority of participants were aged 25–30 years (41.1%), with a mean age of 26.8 ± 4.5 years, indicating that first-trimester vaginal bleeding was most commonly encountered during the peak reproductive years. Similar age distributions have been reported in previous studies evaluating early pregnancy bleeding, reflecting the higher incidence of pregnancy during this age group (1,2).

Multigravida women constituted a slightly higher proportion of the study population (54.4%) than primigravida women, although the difference was modest. This observation is consistent with previous reports suggesting that first-trimester bleeding can occur irrespective of gravidity.

The most frequent clinical diagnosis in the present study was threatened abortion (54.4%), followed by incomplete abortion (17.8%) and missed abortion (13.9%). These findings are comparable with published literature and current recommendations from the American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG), which recognise threatened miscarriage as the most common clinical presentation among women with first-trimester vaginal bleeding (8–10).

A significant increase in mean PT was observed across the different clinical diagnoses, with the lowest values recorded among women with threatened abortion and the highest values among those with inevitable abortion. This finding suggests that worsening clinical presentation is associated with greater alterations in the coagulation profile. Similar observations have been reported by Knez et al., who demonstrated prolonged coagulation parameters among

women experiencing severe first-trimester bleeding and pregnancy loss (5). Although the present study did not investigate the underlying mechanisms responsible for these changes, prolonged PT may reflect alterations in coagulation associated with increased bleeding severity.

The present study also demonstrated a progressive increase in mean INR with increasing severity of vaginal bleeding. Women with severe bleeding had significantly higher INR values than those with mild bleeding. Although the mean INR values remained only mildly elevated, the observed trend indicates an association between bleeding severity and coagulation status. Similar findings have been reported in previous studies evaluating women with spontaneous abortion and significant vaginal bleeding, in which higher INR values were observed among women with greater blood loss (11).

Platelet count showed a progressive decline with increasing severity of vaginal bleeding. Women with severe bleeding had the lowest mean platelet count, whereas those with mild bleeding had the highest values. Although the mean platelet counts remained within or near the lower end of the normal laboratory range, the observed decline suggests increasing platelet consumption or haemostatic activation with worsening bleeding severity. These findings are consistent with previous reports indicating that lower platelet counts may accompany more severe obstetric bleeding and should be interpreted in conjunction with other clinical and laboratory findings (6,12–15).

Abnormal coagulation parameters were identified in a considerable proportion of the study population. Prolonged PT was the most frequently observed abnormality, followed by elevated INR and reduced platelet count. These findings highlight the potential value of routine coagulation assessment in women presenting with moderate-to-severe first-trimester vaginal bleeding. Early laboratory evaluation, together with clinical examination and ultrasonography, may assist clinicians in identifying women who require closer monitoring and timely intervention.

More than half of the pregnancies (56.7%) continued during the follow-up period, while approximately one-third resulted in spontaneous abortion and a smaller proportion required surgical evacuation. These findings emphasise that although first-trimester vaginal bleeding is associated with an increased risk of pregnancy loss, continuation of pregnancy remains possible in a substantial proportion of affected women. Therefore, careful clinical evaluation and appropriate follow-up remain essential for optimising maternal and fetal outcomes.

The findings of the present study support the role of PT, INR, and platelet count as useful adjunctive laboratory investigations in the assessment of women presenting with

first-trimester vaginal bleeding. However, these laboratory parameters should be interpreted alongside clinical findings and ultrasonographic evaluation rather than as independent predictors of pregnancy outcome. Further multicentre studies with larger sample sizes and extended follow-up are required to validate these findings and to better define the prognostic value of coagulation parameters in early pregnancy bleeding.

STUDY LIMITATIONS

This was a single-centre study, which may limit the generalizability of the findings. Only PT, INR, and platelet count were evaluated, while other coagulation parameters were not assessed. Follow-up was limited to pregnancy outcomes, and potential confounding factors such as nutritional status, inherited thrombophilia, liver dysfunction, and inflammatory disorders were not evaluated. Further multicentre studies with larger sample sizes and comprehensive coagulation profiling are warranted.

CONCLUSION

Women presenting with first-trimester vaginal bleeding demonstrated significant alterations in coagulation parameters, with prolonged PT, elevated INR, and reduced platelet count associated with increasing bleeding severity. Coagulation assessment, alongside clinical evaluation and ultrasonography, may assist in identifying women requiring closer monitoring and timely management.

Recommendations

Routine assessment of PT, INR, and platelet count should be considered, particularly in women presenting with moderate-to-severe first-trimester vaginal bleeding. Further multicentre studies with larger sample sizes and comprehensive coagulation profiling are recommended to validate these findings and establish the prognostic value of coagulation parameters in early pregnancy bleeding.

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Informed Consent

Written informed consent was obtained from all eligible participants before enrolment. Participation was voluntary, and participants were informed of their right to withdraw from the study at any stage without affecting their routine medical care. Participant information was kept confidential and personal identifiers were removed before analysis.

Source of Funding

No external funding was received for this study.

Conflict of Interest

The authors declare that they have no conflict of interest.

Availability of Data

The data generated and analysed during this study are not publicly available because they contain participant-level clinical information but may be made available from the corresponding author on reasonable request, subject to institutional and ethical requirements.

Author Contributions

Dr. Ashwini: Conceptualization, study design, supervision, data collection, data interpretation, and manuscript preparation.

Dr. Arushi Anupriya.: Data collection, imaging assessment, data analysis, and critical revision of the manuscript.

Dr Dilip Kumar.: Data collection, interpretation of findings, literature review, and critical revision of the manuscript.

All authors: Reviewed and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

List of Abbreviations

PT: Prothrombin Time;

INR: International Normalized Ratio;

CBC: Complete Blood Count;

SPSS: Statistical Package for the Social Sciences;

ANOVA: Analysis of Variance;

ICMR: Indian Council of Medical Research;

ACOG: American College of Obstetricians and Gynecologists;

RCOG: Royal College of Obstetricians and Gynaecologists.

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