

Prognosticating First Trimester Vaginal Bleeding: A Case-Control Study Of Obstetric Outcome In A Tertiary Care Center

Keerti Kyalakond¹, Gagandeep Kaur², Saumya Srivastava³, Lakshmikanth H Karegowda⁴, Harramb Mittal^{*5}

¹Associate Professor, Department of Obstetrics and Gynaecology, Kanachur Institute of Medical Sciences, Natekal, Mangaluru

²Specialist Obstetrician and Gynecologist, Department of OBG, Saada Hospital, Sohar.

³Associate Professor, Nitte Institute of Physiotherapy, NITTE (Deemed to be University), Deralakatte, Mangaluru

⁴Professor, Department of Radiology, Kanachur Institute of Medical Sciences, Natekal, Mangaluru

^{5*}Associate Professor, Department of Orthopedics, Kanachur Institute of Medical Sciences, Natekal, Mangaluru

*Corresponding author:

Harramb Mittal

Associate Professor, Department of Orthopedics, Kanachur Institute of Medical Sciences, Natekal, Mangaluru

[Cite this paper as:](#) Keerti Kyalakond, Gagandeep Kaur, Saumya Srivastava, Lakshmikanth H Karegowda, Harramb Mittal, (2025) Prognosticating First Trimester Vaginal Bleeding: A Case-Control Study Of Obstetric Outcome In A Tertiary Care Center. *Journal of Neonatal Surgery*, 14 (10s), 69-81.

ABSTRACT

Aims And Objectives: To evaluate the impact of first-trimester vaginal bleeding as a predictor of adverse pregnancy outcomes.

Material And Methods: A case-control study was conducted for a year, comprising of 80 cases and controls. The cases and controls were followed up and obstetric outcomes were noted which includes missed/complete/incomplete abortion, preterm delivery, premature rupture of membrane (PROM), preterm premature rupture of membrane (PPROM), IUGR, manual removal of placenta, preeclampsia, abruption placenta, placenta previa were tabulated and statistical analysis performed.

Results: Incidence of first trimester vaginal bleeding was 18-20%. Overall, subjects with first trimester bleeding had statistically significant higher risk of preterm delivery [8.75% vs. 1.25%;OR-7.57;P value:0.030], PROM [15% vs. 5%;OR-3.53;P value:0.035], PPRM [8.75% vs. 1.25%;OR-7.57;P value:0.03], abortion [20% vs. 2.5% ;OR- 8.75;P value:0.002]. IUGR [3.75% vs. 2.5%;OR-1.52], pre-eclampsia [5% vs. 2.5%;OR- 2.05], abruption placenta [2.5% vs 1.25%;OR-2.03], manual removal of placenta [5% vs.1.25%;OR-4.15] were not statistically significant. Similarly there was no statistically significant difference in the cesarean section (47.6% vs 47.7%) and vaginal delivery (50.8% vs 52%) in both groups.All babies had normal APGAR.

Conclusion: In the present study, 80% of the subjects continued their pregnancy despite having had threatened abortion in the first trimester. It was found that there was an increased risk of preterm delivery, PROM, PPRM , and abortion which was significant.

Keywords: Threatened miscarriage, first trimester, preterm delivery, subchorionic bleeding

1. INTRODUCTION

Bleeding per vagina in the first trimester of pregnancy is one of the common obstetric problem and one of the causes for emergency admission. It affects approximately 16-25% of first-trimester pregnancies with a fetal loss of approximately 50%⁽¹⁾. When bleeding occurs in the first trimester, about 10-15% may be an ectopic pregnancy, 0.2% may be a hydatidiform mole, 5% may have a termination of pregnancy, and the remaining 50% will continue beyond 20 weeks. Approximately 18% of women with vaginal bleeding in the first trimester have a sonographically demonstrable subchorionic hematoma, which signifies underlying placental dysfunction⁽²⁾. Studies have shown that bleeding per vagina in the first trimester may be associated with various adverse pregnancy outcomes like missed abortion, complete abortion, incomplete abortion, pre-eclampsia, abruption placenta, preterm delivery, placenta previa, preterm premature rupture of membranes, premature rupture of membranes, intrauterine growth restriction, small for gestational age, manual removal of placenta⁽³⁾.

The first trimester of pregnancy is a dynamic period that spans ovulation, fertilization, implantation, and organogenesis. Complications occurring during this period pose a diagnostic and management challenge to the obstetrician. The important causes of first trimester vaginal bleeding are as follows, failing intrauterine pregnancy, ectopic gestation, molar pregnancy, cervical causes like polyp, growth, erosion, implantation bleeding. Identification of cases with threatened miscarriage and differentiation of these cases with other cases of non-viable intrauterine pregnancies helps the obstetrician in counseling of the couple and gives reassurance to the patient.

Hence, we conducted the study to observe the distribution of cases of viable pregnancies and non-viable pregnancies in women presenting with first-trimester vaginal bleeding in our hospital and also to observe the presence of complications during follow up of women with a threatened miscarriage so that in future this can help us for better counseling and better antenatal care for these couples.

2. MATERIAL AND METHODS

The study included 80 pregnant patients with obstetrical causes of bleeding per vaginum in the first trimester presented to a tertiary care center over one year and 80 controls who did not have bleeding per vagina in the first trimester of pregnancy. Patients with non-obstetric causes of bleeding, more than 12 weeks of gestation presenting with bleeding per vagina, multiple pregnancy, molar pregnancy, ectopic pregnancy, uterine anomalies, pregnancy complicated with medical disorders like SLE, APLA, etc. were excluded from the study.

The relevant parameters were recorded in a pre-designed proforma which included identification data, demographic characteristics, general physical examination, and obstetrical examination. Cases and controls were selected consecutively. Written informed consent and Institutional ethical committee clearance was taken.

Data Analysis:

All categorical variables were summarized using percentages. Mean and S/D ratio were used to summarize continuous variables. Case and control groups were compared age-wise, parity wise and BMI wise and were summarized as frequency with percentages. Among cases, based on history, clinical examination, ultrasound examination subjects were distributed as frequency with percentages. Cases who have sub-chorionic hematoma were followed up using ultrasound and summarized as frequency with percentages. A comparison between cases and controls was carried out using the chi-square test for categorical variables and t-test for continuous variables by cross-tabulation. Logistic regression was carried to identify risk factors for first trimester vaginal bleeding study with complications such as preterm labor, PROM, PPRM, IUGR, MRP, pre-eclampsia, abortion as independent variables. Associations were measured using odd's ratio with a 95% confidence interval. Multi variant logistic variables was used to identify the risk factors. P-value of <0.05 was considered as statistically significant.

Statistical software:

The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat12.1, And R environment ver.2.11.1 were used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables, etc.

3. OBSERVATIONS AND RESULTS OF DATA ANALYSIS

The total number of subjects (cases) included in this study was 80. The comparison of this group was done with 80 other pregnant women who delivered within the same study period and who did not have a history of bleeding during the first trimester (Controls).

Table 1 shows an age-wise comparison between cases and controls. Age ranged from 20 to 40yrs in both the groups. In the study group, the maximum percentage (50 %) of subjects were in the age group of 26-30 yrs. while the least common (5 %) age group was between 36 to 40 years. The control group also followed the same pattern of distribution with the highest percentage being between 26-30 yrs. (52.5%) and the least common group being 36-40 yrs. (1.2%). Thus both the groups were age-matched with a p-value of 0.077 (which is not significant). The mean $\pm$ S.D of age in cases was 28.7 $\pm$ 4.0 years and in controls was 26.63 $\pm$ 3.37 years.

Table 1 - Age-wise comparison between Cases and controls:

Age in years	Cases (N=80) N (%)	Controls (N=80) N (%)
20-25	16(20%)	26(32.5%)
26-30	40(50%)	42(52.5%)
31-35	20(25%)	11(13.8%)
36-40	4(5%)	1(1.2%)

Statistical method : independent t test, P=0.07 (not significant)

In the **Table 2** parity wise distribution of subjects is shown among the study groups. Among the cases, 57.50 % were primigravida while 42.5 % were multigravida in which gravida 2 was 21.20 %, gravida 3 was 13.8%, gravida 4 were 3.8 % and gravida 5 were 3.8%. Among controls, 58.8 % of the subjects were primigravida, and the remaining 41.2% of women were multigravida. Both the groups were gravida matched with a p-value of 0.116 which is not significant.

Table 2 –Parity index comparison between case and control group:

Gravida	Case group (N=80) N (%)	Control Group (N=80) N (%)
Gravida 1	46(57.5%)	47(58.8%)
Gravida 2	17(21.2%)	24(30%)
Gravida 3	11(13.8%)	09(11.2%)
Gravida 4	03(3.8%)	00
Gravida 5	03(3.8%)	00
Total	80(100%)	80(100%)

Samples are Parity matched with P=0.116

Statistical method:Cross Tab

Table 3 gives BMI comparison between cases and controls. In both groups, BMI ranged from <18.5 to >30. In the case group, the highest percentages (78.75 %) of subjects were having a BMI between 18.5 &25. The control group also followed the same pattern of distribution where the highest percentages (75%) of subjects were having a BMI between 18.5 &25. Thus both the study groups were BMI matched with a p-value of 0.997 (which is not significant).

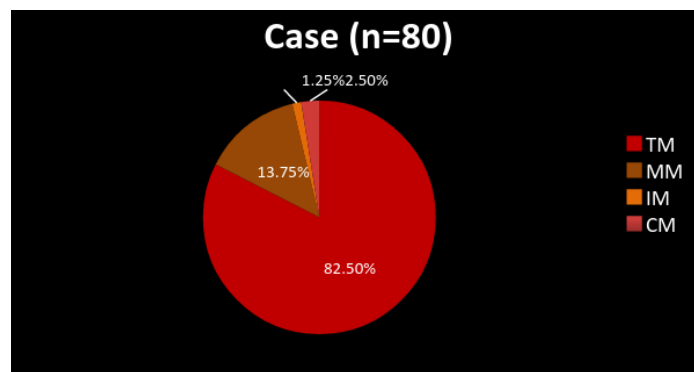
In the present study, the final diagnosis was made based on history, clinical examination, and ultrasonographic evaluation. Total subjects were categorized into 4 groups after satisfying inclusion and exclusion criteria as shown in **Pie diagram 1**. Out of 80 subjects, 66 subjects (82.5 %) had threatened abortion, 11 subjects (13.75%) had missed abortion (based on ultrasonography), 01 subjects (1.25%) had incomplete abortion and 2 subjects (2.5 %) had a complete abortion.

Table 3 –Body mass index comparison between case and control group:

BMI(Kg/m2)	Case group (N=80) N (%)	Control Group(N=80) N (%)
<18.5	07(8.75%)	10(12.5%)
18.5 - 25	63(78.75%)	60(75%)
25 -30	09(11.25%)	10(12.5%)
>30	01(1.25%)	00
Total	80(100%)	80(100%)

Statistical method:Cross Tab Samples are BMI matched with a P-value of 0.997 (Not significant)

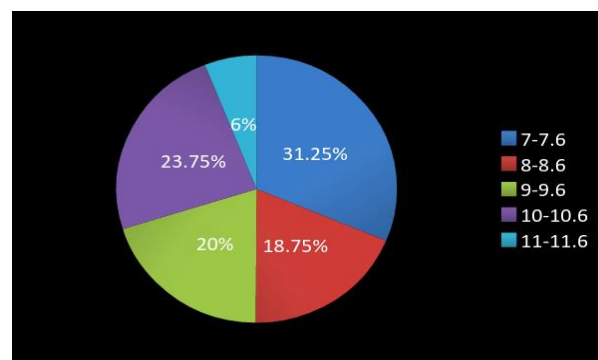
Pie diagram 1: Distribution of study subjects based on diagnosis



Threatened miscarriage-TM, Missed miscarriage-MM, Incomplete miscarriage-IM, Complete miscarriage-CM.

As depicted in the **Pie diagram 2** the maximum numbers of cases having bleeding per vagina during the first trimester were between 7weeks to 7weeks 6 days (31.25%) while the least number of cases were between 11weeks to 11weeks 6days (6 %). 91.2% of the subjects in the study group and 83.8% in the control group had spontaneous conception. 8.8% in the study group and 16.2% in the control group conceived after infertility treatment ($P=0.151$). 26.2% of the study group and 17.5% in the control group had a history of previous abortion ($P=0.181$).

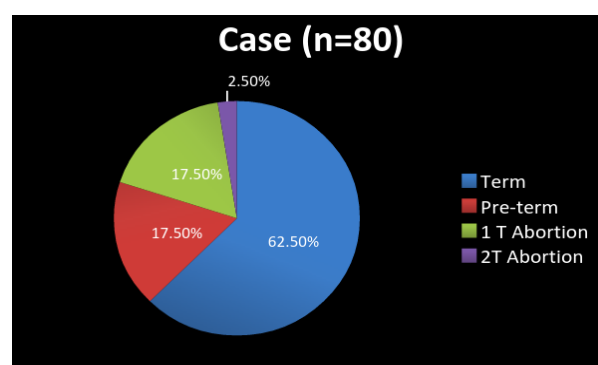
Pie diagram 2: Period of Gestation at the time of bleeding among cases:



Gestational age in weeks.

Pie diagram 3 shows the pregnancy outcome of cases. Out of 80 subjects, 64 subjects (80 %) had a favorable outcome whose pregnancy continued beyond 28 weeks of gestation age (viable), 2 (2.5%) subjects aborted in 2nd trimester. Remaining 14 (17.5%) subjects presented with miscarriage (unfavorable outcome) in the first trimester. Out of 64 subjects who had a favorable outcome, 50 subjects (62.5 %) continued till term (≥ 37 weeks GA) while 14 subjects (17.50%) had preterm delivery.

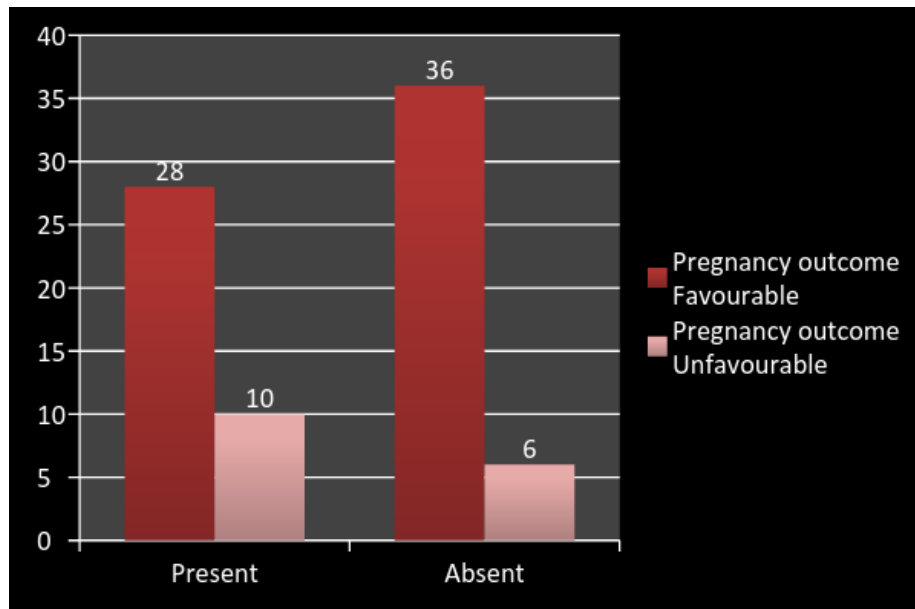
Pie diagram 3: Pregnancy outcome of cases



1T-1st trimester abortion, 2T-2nd trimester abortion.

The outcome of pregnancy in cases with sub-chorionic hematoma is shown in **Bar chart 1**. Favorable outcome refers to the pregnancy that continued beyond viability and unfavorable outcome is that which ended in a miscarriage before the period of viability (28 weeks). Among 80 subjects, 38 (47.5 %) had a hematoma on ultrasound scanning in which 28 subjects had a favorable outcome and 10 subjects had an unfavorable outcome. Hematoma was absent in the rest of the 42 threatened miscarriages (52.5 %) among which 36 subjects had favorable and 6 subjects had unfavorable outcomes. Among 38 subjects who had a hematoma, in 10 subjects hematoma resolved, in 10 subjects they increased in size, in 6 subjects they decreased in size and remaining in 12 subjects their size remained the same.

Bar chart 1: Outcome of pregnancy in cases with Sub-chorionic haematoma:



Favourable outcome refers to the pregnancy that continued beyond viability and unfavorable outcome is that which ended in a miscarriage before the period of viability (28 weeks). Among 80 subjects, 38 (47.5 %) had hematoma on ultrasound scanning in which 28 subjects had favorable outcome and 10 subjects had unfavorable outcome. Hematoma was absent in rest of the 42 threatened miscarriages (52.5 %) among which 36 subjects had favorable and 6 subjects had unfavorable outcomes. Among 38 subjects who had haematoma, in 10 subjects haematoma resolved, in 10 subjects they increased in size, in 6 subjects they decreased in size and remaining in 12 subjects their size remained same.

As shown in **Table 4** out of 64 pregnancies which continued beyond the viability period, 28 subjects had an intrauterine hematoma in which preterm delivery was seen in 6 (21.2%) subjects. Among the rest 36 subjects with no hematoma, 8(22.3%) subjects had preterm delivery.

Table 5 shows the complications in cases were compared with those in controls who delivered during the same study period. 14 out of 80 cases had various types of miscarriages in the first trimester which ended the pregnancy. Rests (66 cases) were followed up until the delivery and complications if the present were compared with complications in the control group.

Table 4-Preterm delivery in cases with an intrauterine haematoma in first trimester:

Preterm delivery	Haematoma (N=64)	
	Present	Absent
Present	6 (21.2%)	8 (22.3%)
Absent	22 (78.8 %)	28 (77.7%)
Total	28	36

(N=80-16, where 16 is number of abortions hence n =64)

Table 5: Comparison of complications between cases and controls:

Complications	Cases(n=80)	Controls(n=80)	P-value	Odds ratio	95% Confidence interval
PTL	07 (8.75%)	01(1.25%)	0.030*	7.57	0.92-63.06
PROM	12(15%)	04(5%)	0.035*	3.53	1.032-10.89
PPROM	07(8.75%)	01(1.25%)	0.030*	7.57	0.91-63.06
IUGR	03(3.75%)	02(2.5%)	0.650	1.52	0.24-9.34
MRP	04(5%)	01(1.25%)	0.173	4.15	0.454-38.04
PE	04(5%)	02(2.5%)	0.405	2.05	0.365-11.58
AP	02(2.5%)	01(1.25%)	0.559	2.03	0.18-22.79
ABORTION	16(20%)	02(2.5%)	0.002*	8.27	1.82-37.73
NO COMPLICATIONS	25(31.5%)	66(82.5%)			

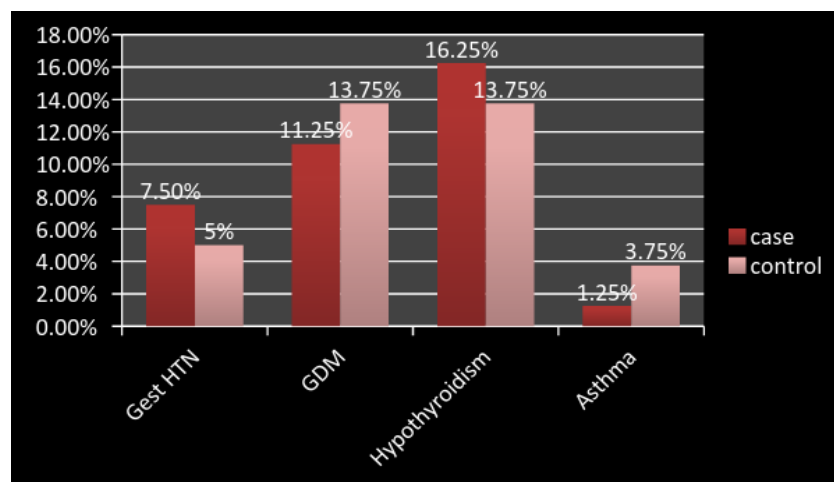
P * less than 0.05 considered significant .Statistical test used:Cross Tab

Overall, subjects with first trimester bleeding had higher risk of preterm delivery [8.75% vs. 1.25% with OR 7.57], PROM [15% vs. 5% with OR 3.53], PPRM [8.75% vs. 1.25% with OR 7.57], abortion [20% vs. 2.5% with OR 8.75], IUGR [3.75% vs. 2.5% with OR 1.52], pre-eclampsia [5% vs. 2.5% with OR 2.05], abruption placenta [2.5% vs 1.25% with OR 2.03] and MRP [5% vs.1.25% with OR 4.15].

Among all complications, higher incidence of preterm delivery, PROM, PPRM, and abortions in the cases were statistically significant as compared to the controls with a P-value of 0.030, 0.035, 0.030, and 0.002 respectively.

In **Bar chart 2** among 80 cases, 6(7.5%) subjects had gestational hypertension, 9(11.25%) subjects had GDM, 13 (16.25%) subjects had hypothyroidism and 1(1.25%) subject had asthma. Among 80 controls, 4 (5%) subjects had gestational hypertension, 11(13.75%) subjects had GDM, 11(13.75%) subjects had hypothyroidism and 3 (3.75%) subjects had asthma. 47.6% in the study group and 47.7% in the control group underwent acesarean section.50.8% in the study group and 52% in the control group had vaginal delivery. Among them, 1.6% in the study group and 1.3% in the control group had an instrumental vaginal delivery. None of the above parameters were statistically different in both groups.

Bar chart 2: Prevalence of medical disorders contributing to complications among case and controls:

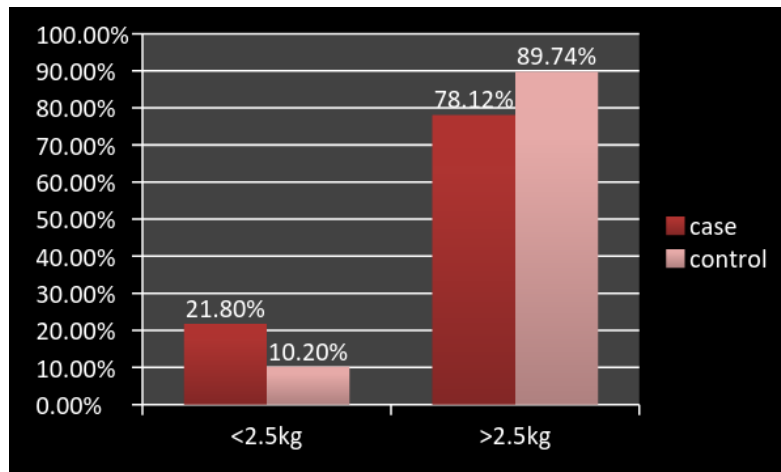


P value: 0.337(Statistically not significant) statistical method used: Cross Tab

In a **Bar chart 3** among the cases (80), a total of 64 pregnancies continued beyond viability. 14(21.8%) subjects delivered babies weighing <2.5kg and 50(78.12%) subjects delivered babies weighing >2.5kg. Among controls, 8(10.2%) subjects delivered babies weighing <2.5kg and 70 (89.8%) subjects delivered babies weighing >2.5kg, while 2 subjects (2.5%) had miscarriage. The difference in the birth weight among the cases and controls was not statistically significant ($P=0.066$) in the present study. 98.4% in the study group and 100% of babies in the control group had normal APGAR.

Evaluation of management of the cases was done in **Table 6**. Out of a total of 80 subjects of threatened miscarriage, 69 subjects were managed with bed rest and progesterone supplement. 11 cases had missed abortions who were managed either with medical termination (7 cases) or dilatation & evacuation (D&E) (4 cases). One out of 69 cases on progesterone supplement had an incomplete miscarriage which was managed by D&E. Two out of 69 cases had a complete miscarriage and were followed up with no intervention. Two patients had spontaneous abortion in the second trimester.

Bar chart 3: Comparison of Birth weight among cases and controls



Among total cases ($N=80$), 16 subjects aborted. Hence $n=64$. Among total controls ($N=80$), 2 subjects aborted. Hence $n=78$. P value-0.066 which is not statistically significant.

Statistical method used : Cross Tab.

Table 6: Management of subjects with first-trimester vaginal bleeding

Management	Number of patients (N=80)
Antenatal check-up	80
Progesterone supplement	60
HCG supplement	09
Dilation & Evacuation	5*
Medical management for termination of pregnancy	7

*4 cases had missed abortion and 1 case which was on progesterone supplementation had an incomplete miscarriage.

4. DISCUSSION

The first trimester of pregnancy is a unique and most critical period of human development where the remarkable transformation of a single cell into a recognizable human being occurs. The first definitive sonographic finding to suggest early pregnancy is a visualization of the gestational sac at around 5th weeks of gestation. As sac enlarges it compresses the central cavity echo complex giving rise to characteristic double decidual sac sign (DDSS) Figure 1. The yolk sac is the first

anatomical structure identified within the GS. Using a transvaginal scan (TVS) it is always visible by 5.5 weeks (Mean sac diameter (MSD) 8 mm) and transabdominal sonography (TAS) by 7 weeks gestational age (GA) (MSD 20mm) Figure 2. . The presence or absence of the yolk sac has a strong predictive value for poor pregnancy outcomes. Cardiac activity by TVS should be detected routinely when an embryo attains a length of 4 to 5 mm. This corresponds to a GA of 6 to 6.5 weeks (Figure 3). An early pregnancy failure can be diagnosed by the absence of a visible yolk sac with a mean sac diameter of 13 mm, the absence of a visible embryo with a mean sac diameter of 20 mm (Figure 4), the absence of cardiac activity with an embryo measuring 5 mm or more in maximal length or the presence of an empty amnion.

In our study mean age in the study group was 28.7 ± 4.0 years and in controls, 26.63 ± 3.37 years. 70% belonged to the 20-30 year age group which is comparable to the study done by Seyedeh Hajar Sharami et al ⁽³⁾ . Women older than 34 years are one and one half to five times more likely to miscarry than younger women . Risk of miscarriage increases with an increase in maternal age ⁽⁴⁾ . In our study, we did not find any statistically significant association between the maternal age and miscarriage probable as the majority of our patients belonged to the younger age group. In our study group, 57.50 % were primigravida and in controls, 58.8% were primigravida comparable to the study done by Seyedeh Hajar Sharami et al ⁽³⁾ . The risk of spontaneous miscarriage increases with parity ⁽⁵⁾ . 78.75 % had normal BMI in the study group.

Various causes of failing intrauterine pregnancy include spontaneous miscarriage, early embryonic demise, anembryonic pregnancy (eg: Figure 5, 6). Spontaneous miscarriage can either be threatened, inevitable, incomplete, or complete. In our study total subjects were categorized into 4 groups after satisfying inclusion and exclusion criteria as shown in Pie diagram 1. 82.5 % had threatened abortion, continued their pregnancy to viability, rest of them aborted.

Among 80 subjects, 38 (47.5 %) had a hematoma on ultrasound scanning in which 28 subjects had a favorable outcome and 10 subjects had an unfavorable outcome. Prevalence of intrauterine hematoma in threatened miscarriage subjects in the present study was 47.5 % which is higher than the study done by Poulouse et al ⁽⁶⁾ . This higher prevalence of intrauterine hematoma in our study could be due to the departmental protocol followed by us in conducting ultrasound examinations for all patients presenting with bleeding per vagina in the first trimester and sub-chorionic hematoma detection. Patients without sub-chorionic hematoma had a more favorable outcome as shown in Bar chart 4. Heller HT et al ⁽⁷⁾ showed that in the presence of hematoma the risk of miscarriage was 2.6 times more. In the present study, the miscarriage rate was 26.31 % in the presence of hematoma and 14.2% in its absence. Thus, the miscarriage rate in the presence of hematoma (eg: Figure 7) was statistically significant ($P < 0.05$) in the present study, correlating with Heller HT. In this study they also found that the size of the hematoma estimated as a fraction of gestational sac size significantly correlated with first-trimester pregnancy loss. The earlier in pregnancy an subchorionic haematoma is detected, the higher the rate of subsequent pregnancy failure ⁽⁷⁾ . Ayser Hashem et al ⁽⁸⁾ did a study on perinatal outcomes in women with retroplacental haematoma and subchorionic haematoma. The presence of an intrauterine hematoma during the first trimester increased the risk of adverse pregnancy outcome as preterm delivery, IUGR, abruption, low birth weight, cesarean section rate, low Apgar score . However presence of subchorionic haematoma did not increase the risk of these adverse pregnancy outcome ⁽⁸⁾ . In the present study, the rate of preterm delivery in cases with subchorionic hematoma was 21.2%, while the rate in cases without hematoma was 22.23 % . Thus the presence of hematoma did not make any difference in the rate of preterm delivery. There was no statistical difference concerning preterm delivery.

Figures 1: TAS showing Double decidual sac sign. (Image taken from the hospital where the study is conducted).



Figure 2: TVS showing yolk sac within GS in early pregnancy. (Image taken from the hospital where the study is conducted).



Figure 3: TAS showing GS containing yolk sac and embryo. (Image taken from the hospital where the study is conducted).



Figure 4: TVS showing subchorionic Hemorrhage. (Image taken from the hospital where the study is conducted).



Figure 5: Empty GS (Anembryonic pregnancy). (Image taken from the hospital where the study is conducted).

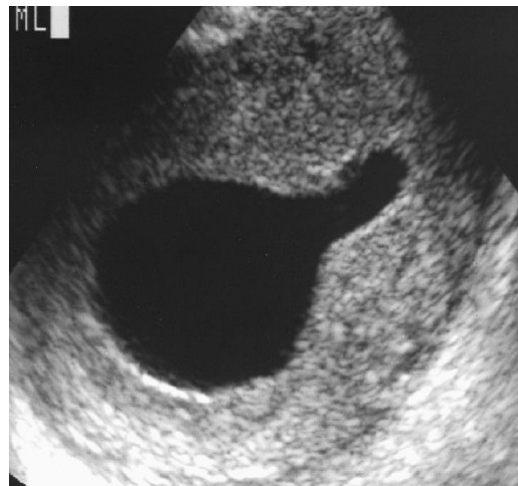


Figure 6: Embryonic demise / Dead embryo / calcified yolk sac. (Image taken from the hospital where the study is conducted).



Vaginal bleeding followed by thrombin production can cause a proteolytic cascade which leads to fetal membranes destruction and finally PROM and preterm labour⁽⁹⁾. Thrombin, the most abundant coagulation factor in blood, is associated with uterine myometrial contraction. Thrombin induces myometrial contractions by two mechanisms, including direct activation of myosin and indirect increases in prostaglandin synthesis⁽⁹⁾. There is evidence of defective implantation in these patients, characterized by thinner and fragmented trophoblast cells and reduced cytotrophoblasts invasion of the spiral arteriole. Complications in later stages of pregnancy such as pre-eclampsia, preterm labor and PPRM have been seen to be associated with impaired implantation and failure of the physiological invasion of the spiral arterioles⁽¹⁰⁾. This explains why these complications are more common in patients with a history of bleeding in the first trimester.

An iron deposit due to bleeding may provoke the production of excessive oxidative stress in these patients, which may be related to increased chances of preterm delivery, PROM, and pre-eclampsia⁽¹⁰⁾. In the present study as shown in table 5, there was a statistically significant association with vaginal bleeding in the first trimester and preterm delivery (P-value 0.030 and OR- 7.57), PPRM (p-value- 0.030 and OR-7.57), PROM p-value-0.035 and OR-3.53) and abortion (p-value 0.002 and OR 8.27). Among the study group and control groups, due to associated medical disorders (uncontrolled glycaemic control in GDM, severe pre-eclampsia) and other factors (oligohydramnios, fetal distress) labor was induced before 37 completed weeks, which may be the confounding factor for preterm delivery.

Women with first trimester bleeding have a higher likelihood of miscarriage. The risk of miscarriage depends upon gestational age at bleeding, amount, and number of days of bleeding and is diminished after confirmation of viability⁽¹⁰⁾. The prognosis of a patient who bleeds vaginally during pregnancy varies indirectly according to both the amount of bleeding and gestation age at the time of bleeding.

Women with threatened miscarriage had a significantly higher incidence of APH due to placenta praevia or APH of unknown origin when compared with those without first- trimester bleeding⁽¹¹⁾. Manual removal of retained placenta appears to be increased in women who had bleeding in the first trimester. A significant association exists between first trimester bleeding

and intrauterine growth retardation (IUGR). The risk of having a baby with IUGR is 1.54 times in women with first trimester threatened miscarriage ⁽¹¹⁾.

However, in our study, the risk of preeclampsia, abruptio placenta, IUGR, and MRP was not found to be statistically significant in threatened miscarriage subjects as shown in Table 5. As there were, fewer number of such events in our study population, it could be a limitation in our study. By increasing the sample size, they may become statistically significant.

The overall risk of having a low-birth-weight baby is higher in women with bleeding in the first trimester than in women who do not ⁽¹¹⁾. The risk varies from 1.1 to 3.7 across the different studies. 21.8% of subjects and 10.2% of controls delivered the baby <2.5Kg which was not statistically significant. Preterm birth was the cofounding factor for low birth weight. Women presenting with heavy bleeding are at higher risk of small for gestation babies whereas women with light bleeding are not at such an increased risk ⁽⁵⁾.

47.6% in the study group and 47.7% in the control group underwent acesarean section. 50.8% in the study group and 52% in the control group had vaginal delivery. Among them, 1.6% in the study group and 1.3% in the control group had an instrumental vaginal delivery. The P-value was 0.984 which was statistically not significant. Perinatal deaths are observed to be nearly twice as frequent in women who experience threatened miscarriage when pooled across different study ⁽¹¹⁾. However, in our study no perinatal death was present. 98.4% in the study group and 100% of babies in the control group had normal APGAR. Thus, in our study, mode of delivery and APGAR score of the new-born were not influenced by the sub-chorionic bleeding in the first trimester. In a study done by Samarakkody et al. ⁽¹²⁾, there was no statistically significant difference noted between the study and control groups regarding the incidence of placental abruption, placenta praevia, retained placenta, rate of acesarean section, rate of instrumental delivery, the incidence of neonatal death, Apgar score <7 at 5 minutes and rate of admission to neonatal intensive care unit. This study is comparable to our study.

Progesterone (“pregnancy hormone”) is crucial in the maintenance of pregnancy as it is involved in modulation of the maternal immune response, suppression of inflammatory response, reduction of uterine contractility, improvement of uteroplacental circulation and luteal-phase support ⁽¹³⁾. In early pregnancy, progesterone is responsible for preparing the endometrium for implantation and maintenance of the gestational sac in the uterus ⁽¹⁴⁾.

In the present study out of a total of 80 subjects of threatened miscarriage, 69 subjects were managed with bed rest and progesterone supplement. 11 cases had missed abortions who were managed either with medical termination (7 cases) or D&E (4 cases). One out of 69 cases on progesterone supplement had an incomplete miscarriage case which was managed by dilatation & evacuation. Two out of 69 cases had a complete miscarriage and were followed up with no intervention. However, progesterone didn’t show any significant benefit in our study.

Limitation of the study

The present study is a case-control study with a small sample size. In our study we didn’t categorize the vaginal bleeding according to the severity and number of episodes of bleeding, second trimester bleeding was not taken into account. Hence large randomized controlled trials are required to conclude.

5. CONCLUSION

Though bleeding in the first trimester of pregnancy is a common complaint presented by many women in the present study, 80% of the subjects continued their pregnancy despite having had threatened miscarriage in the first trimester. In the present study, it was found that there was an increased risk of preterm delivery, PPRM, PROM, and abortion which was significant. The risk of preeclampsia, abruptio-placenta, IUGR, and manual removal of the placenta were not found to be statistically significant in threatened miscarriage subjects in the present study. In the present study prevalence of intrauterine hematoma was 47.5% among threatened miscarriage subjects. The presence of sub-chorionic hematoma may not always mean a poor prognosis but in the present study, the miscarriage rate was 26.31 % in the presence of hematoma and it was 14.2% in the absence of hematoma. Thus, the miscarriage rate concerning the presence of hematoma showed statistical significance. But no difference in the rate of preterm deliveries was found in subjects with and without hematoma. First trimester bleeding did not influence the mode of delivery and APGAR score of the new-born in the present study. Our treatment protocol for women with threatened miscarriage was progesterone supplementation and HCG supplementation. This study has not revealed any definite conclusion regarding the benefits of this treatment.

List Of Abbreviations

TVS: Transvaginal sonography

TAS: Transabdominal sonography

YS: Yolk sac

GS: Gestational sac

GA: Gestational age

CRL: Crown Rump Length
BO: Blighted ovum
MM: Missed miscarriage
IM: Incomplete Miscarriage
CM: Complete miscarriage
PTD: Preterm delivery
APH: Antepartum hemorrhage
PPROM: Premature preterm rupture of membrane
PROM: Premature rupture of membrane
PE: Preeclampsia
AP: Abruptio placenta
MSD: Mean sac diameter
SD: Standard deviation
BMI: Body mass index
POG: Period of gestation
MRP: Manual removal of placenta
IUGR: Intrauterine growth retardation
GDM: Gestational diabetes mellitus
GTN: Gestational Hypertension
P: Progesterone
HCG: Human Chorionic Gonadotropin
D&E: Dilatation and evacuation
OR: Odds ratio
BPM: Beats per minute

Figure Legends

Figures 1: TAS showing Double decidual sac sign. (Image taken from the hospital where the study is conducted).
Figure 2: TVS showing yolk sac within GS in early pregnancy. (Image taken from the hospital where the study is conducted).
Figure 3: TAS showing GS containing yolk sac and embryo. (Image taken from the hospital where the study is conducted).
Figure 4: TVS showing subchorionic Hemorrhage. (Image taken from the hospital where the study is conducted).
Figure 5: Empty GS (Anembryonic pregnancy). (Image taken from the hospital where the study is conducted).
Figure 6: Embryonic demise / Dead embryo / calcified yolk sac. (Image taken from the hospital where the study is conducted).
Pie diagram 1: Distribution of study subjects based on diagnosis
Pie diagram 2: Period of Gestation at the time of bleeding among cases:
Pie diagram 3: Pregnancy outcome of cases
Bar chart 1: Outcome of pregnancy in cases with Sub-chorionic hematoma:
Bar chart 2: Prevalence of medical disorders contributing to complications among case and controls:
Bar chart 3: Comparison of Birth weight among cases and controls

Table Legends

Table 1 – Age-wise comparison between Cases and controls
Table 2 –Parity index comparison between case and control group
Table 3 –Body mass index comparison between case and control group

Table 4-Preterm delivery in cases with an intrauterine hematoma in the first trimester

Table 5: Comparison of complications between cases and controls

Table 6: Management of subjects with first-trimester vaginal bleeding

Declaration Document

Conflicting interests: None

Funding: None

Ethical approval: Ethical approval was taken from the Institutional Ethical Committee (MUEC/01/2014-15)

Informed consent: Taken from all the participants

Guarantor: Dr Nivedita Hegde

Contributorship: Data was collected by Dr. K K. Ultrasound examinations were done by Dr. L H K. Manuscript was prepared by Dr. N H and Dr. S B S

Acknowledgments: None

REFERENCES

- [1] Wittels KA, Pelletier AJ, Brown DF, Camargo Jr CA. United States emergency department visits for vaginal bleeding during early pregnancy, 1993-2003. *American journal of obstetrics and gynecology*. 2008;198(5):523. e1-. e6.
- [2] James DK, Steer PJ, Weiner CP, Gonik B, Robson SC. High-risk pregnancy: management options: Cambridge University Press; 2017.
- [3] Sharami SH, Darkhaneh RF, Zahiri Z, Milani F, Asgharnia M, Shakiba M, et al. The relationship between vaginal bleeding in the first and second trimester of pregnancy and preterm labor. *Iranian journal of reproductive medicine*. 2013;11(5):385.
- [4] Magnus MC, Wilcox AJ, Morken N-H, Weinberg CR, Håberg SE. Role of maternal age and pregnancy history in risk of miscarriage: prospective register based study. *bmj*. 2019;364.
- [5] Weiss JL, Malone FD, Vidaver J, Ball RH, Nyberg DA, Comstock CH, et al. Threatened abortion: a risk factor for poor pregnancy outcome, a population-based screening study. *American journal of obstetrics and gynecology*. 2004;190(3):745-50.
- [6] Poulouse T, Richardson R, Ewings P, Fox R. Probability of early pregnancy loss in women with vaginal bleeding and a singleton live fetus at ultrasound scan. *Journal of obstetrics and gynaecology*. 2006;26(8):782-4.
- [7] Heller HT, Asch EA, Durfee SM, Goldenson RP, Peters HE, Ginsburg ES, et al. Subchorionic hematoma: correlation of grading techniques with first-trimester pregnancy outcome. *Journal of Ultrasound in Medicine*. 2018;37(7):1725-32.
- [8] Hashem A, Sarsam SD. The impact of incidental ultrasound finding of subchorionic and retroplacental hematoma in early pregnancy. *The Journal of Obstetrics and Gynecology of India*. 2019;69(1):43-9.
- [9] Nishimura F, Mogami H, Moriuchi K, Chigusa Y, Mandai M, Kondoh E. Mechanisms of thrombin-Induced myometrial contractions: Potential targets of progesterone. *Plos one*. 2020;15(5):e0231944.
- [10] Johns J, Hyett J, Jauniaux E. Obstetric outcome after threatened miscarriage with and without a hematoma on ultrasound. *Obstetrics & Gynecology*. 2003;102(3):483-7.
- [11] Saraswat L, Bhattacharya S, Maheshwari A, Bhattacharya S. Maternal and perinatal outcome in women with threatened miscarriage in the first trimester: a systematic review. *BJOG: An International Journal of Obstetrics & Gynaecology*. 2010;117(3):245-57.
- [12] Samarakkody S, Gunawardena K. A prospective cohort study to assess the association between early pregnancy bleeding and risk of poor pregnancy outcome. *Sri Lanka Journal of Obstetrics and Gynaecology*. 2019;41(1).
- [13] Di Renzo GC, Giardina I, Clerici G, Brillo E, Gerli S. Progesterone in normal and pathological pregnancy. *Hormone molecular biology and clinical investigation*. 2016;27(1):35-48.
- [14] Czyzyk A, Podfigurna A, Genazzani AR, Meczekalski B. The role of progesterone therapy in early pregnancy: from physiological role to therapeutic utility. *Gynecological Endocrinology*. 2017;33(6):421-4.