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A PROSPECTIVE OBSERVATIONAL STUDY OF MATERNAL AND PERINATAL OUTCOME IN WOMEN PRESENTING WITH BLEEDING IN THE FIRST TRIMESTER OF PREGNANCY IN THE TERTIARY CARE HOSPITAL.

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ABSTRACT **Aims:** To assess the pregnancy outcome in women presenting with first-trimester bleeding per vaginum and pregnancies which continued beyond 13 weeks of gestation. **Materials And Methods:** This was a prospective observational study done over one year, at a tertiary care hospital in Mumbai. The case group of 100 women presented with a history of bleeding per vaginum in their first trimester were matched for age, parity, and gestational age with 100 women in the control group and were followed prospectively till delivery, the early postpartum period, and pregnancy outcomes were recorded. **Results:** A significant association was found between bleeding in the first trimester and adverse maternal (p-value 0.001) and neonatal outcomes (p-value 0.0001). **Conclusion:** We conclude that more careful, prolonged follow-up of women with early pregnancy bleeding is needed as these bleeding episodes may be associated with adverse pregnancy outcomes.

KEYWORDS : First trimester bleeding per vaginum, Preterm delivery, threatened abortion.

INTRODUCTION

Complications are common during the first trimester and may present with bleeding, pain, or both.[1-2] Uterine bleeding in early pregnancy poses a definite threat to the developing embryo and can cause anxiety to both the patient and the clinician.

Approximately one-fourth of pregnant women will experience bleeding in the first trimester.[2]

Amongst all the women presenting with BPV* in early pregnancy, spontaneous abortion will occur in 50% of those cases. If fetal viability is confirmed on ultrasound examination 95% of these pregnancies may continue to progress[1-2]

A threatened abortion is defined as vaginal bleeding before 20 weeks gestational age in the setting of a positive urine and/or blood pregnancy test with a closed cervical os, without passage of products of conception and with no evidence of fetal or embryonic demise.[1-2]

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 preterm delivery[3-8], preterm premature rupture of membranes (PPROM)*[3-8], placenta previa[5,6], perinatal mortality[8], pre-eclampsia[9], placental abruption[10-12], fetal growth restriction[13] and low birth weight baby[3-13].

The present study analyses whether threatened abortion renders the pregnancy a high-risk pregnancy, the effect of bleeding per vaginum in the first trimester on the maternal and neonatal outcome and to study the maternal characteristics which affect the outcome.

METHODS:

A prospective observational study was done for a duration of 1 year from January 2022 to January 2023 at Nowrosjee Wadia Maternity Hospital, Mumbai.

The cases included approximately 100 women who present to the Emergency Department / USG* Department/ Outpatient Department with a history of bleeding per vaginum in their first trimester full filling the inclusion criteria.

The control group matched for age, parity, and gestational age with the cases, comprised of 100 women who have not experienced bleeding per vaginum in their first trimester.

All the women who presented to the emergency /USG* department with the complaint of BPV* in the first trimester of their pregnancy with ultra-sonographic confirmation of fetal viability and singleton intrauterine gestation were included in the case group.

Those booked for antenatal care in the hospital during the same period were in the control group & matched for maternal age, parity, and gestation and without bleeding per vaginum.

Written, informed consent from the patient & detailed history of the patient was recorded including age, education, menstrual history, last menstrual periods, use of contraceptives, history of infertility treatment, obstetric history, history of previous miscarriage, history of post-coital bleeding, method of pregnancy confirmation, history of pain or passage of clots per vaginum.

Weeks of gestation were defined with the first 6 days after LMP labeled as week 0, the next 7 days considered week 1, the next 7 days considered week 2, and so forth.[15]

Primary assessment of patient visiting emergency department/ USG* department/outpatient department was done and recorded which included general and systemic examination, per speculum examination to rule out other vaginal/cervical pathologies causing BPV*, and per vaginal examination to examine for cervical os status and to see if the product of conception at the cervical os to exclude pregnancy losses at the time of presentation. An ultrasound was done for confirmation of fetal viability and to rule out cases of miscarriage.

For evaluation and quantification of the amount of bleeding, methods suggested in a study- "Vaginal bleeding in early pregnancy: Patterns, predictors, and association with miscarriage" based on the Data from *Right from the Start* (RFTS) [15]. a prospective, community-based pregnancy cohort was used. BPV* was classified as spotting, light bleeding, and heavy bleeding. [15] The heaviness of the episode was defined according to the heaviest flow during the episode compared to a patient's usual flow during a menstrual period.

- A 'spotting' episode was considered to be the one that was only noticed when wiping with a tissue.[15]
- A 'light bleeding' episode was defined as having the heaviest day(s) of flow being lighter than the heavy flow of a usual menstrual period.[15]
- A 'heavy bleeding' episode was defined as having the heaviest day(s) of flow as heavy or heavier than the heavy flow of a usual menstrual period.[15]

Any previous investigation done by the patient for pregnancy confirmation such as evaluation of beta- hCG* levels was noted. The details of the patient were recorded in the Clinical case record form. Transvaginal ultrasound with a (5 MHz) was done to ascertain the location of the pregnancy and confirmation of fetal viability. Intrauterine gestation was assessed for fetal viability.[16]

All the participants in Case and Control groups were followed till the end of pregnancy and one week post-partum to account for complications perinatal period.[17] Maternal outcomes like hypertensive disorders of pregnancy, preterm delivery, preterm premature rupture of membrane (PPROM*), fetal growth restriction (a USG* estimation of fetal weight below the tenth percentile for a given gestational age)[18], placenta abruption, placenta previa, post-partum hemorrhage, and Neonatal Outcome such as low birth rate (<2500 kg- as per the WHO* definition)[19] perinatal death (FSB*/MSB*early neonatal death <7 days

of birth), NICU* admission were recorded for both the groups.

Data was analyzed using SPSS V15.0. Comparison of means of 2 groups was carried out by Student's unpaired t-test for numerical normal data. Fisher Exact Probability tests were applied to compare percentages for categorical data between 2 groups. Chi-square statistical tests were applied to compare percentages among the 2 groups. The p-Value of <0.005 was considered as a test of significance.

RESULTS:

A total of 200 participants were enrolled in the study and divided into two groups referred to as 'Cases' and 'Control' with 100 participants in each group.

The mean maternal age, mean gestational age at birth in weeks, and mean birth weight of babies in the study group were 30.07+4.181 years, 37.2 weeks, and 1.813+109.843 respectively.

Similarly Mean maternal age, mean gestational age at birth in weeks, and mean birth weight of babies in the control group were 29.37+4.101 years, 38.1 weeks, and 2.803+0. 450 respectively. There was a statistically significant difference in gestational age (p-value 0.016) and birth weight (p-value 0.006) of babies between the two groups.

The number of primipara and multipara were 63 and 37, respectively in the case group and 52 and 48 respectively in the control group.

27 participants in the control group and 32 participants in the case group were employed. Poverty has a negative impact on the physical and mental health of the mother leading to repercussions on the development of the fetus and increasing the risk of adverse pregnancy outcomes.[20]

On comparing clinical variables, the pre-pregnancy BMI*[21] of 18 cases and 17 controls were underweight. 7 cases and 4 controls were overweight.

In the case group, 14 participants compared to 8 in the control group had conceived by ART*.

In the case group, 83% of participants reported experiencing nausea in the first trimester, and 7% of participants reported a history of post-coital hemorrhage. Pre Conceptional folic acid was availed by 27 participants in the case group and 44 participants in the control group. (Table 1)

Table 1 – Demographic And Clinical Variables

Demographic and Clinical Variables		Case	Control	p-Value
Mmaternal Mean Ag age(years)		30.07+4.181	29.37+4.101	
Mean G Gestational AgAge(weeks)		37.2	38.1	0.016
MMean Birth wweight(kg)		1.813+1.09	2.803+0.45	0.006
GrGravida status	Prim gravida	63	52	0.112
	Multigravida	37	48	
Edocucation	High school	68	66	0.881
	Graduate	32	34	
Peper Capita InIinome	<10,000	26	50	0.01
	>10,000	73	50	
occupation	Employed	32	27	0.535
	Housewife	68	73	
BBMI*	Underweight	18	17	0.653
	Normal	75	79	
	Overweight	7	4	
Method of Conception	ART*	14	8	0.123
	Spontaneous Conception	86	92	
History of post-Coital Bleeding	No	93	94	0.774
	Yes	7	6	
History of Nausea in the First Trimester	No	17	37	0.00144
	Yes	83	63	
Pre-Conceptional Folic Acid	No	73	56	0.012
	Yes	27	44	
Past Menstrual Cycle	Irregular	30	29	0.876
	Regular	70	71	

Adverse pregnancy outcomes were found to be significantly associated with a history of nausea in the first trimester (p-Value 0.001) and a lack of preconception folic acid consumption (p-Value 0. 01).

Maternal outcomes with no complications were seen in 54 participants in the study group compared to 77 participants in the control group.

Preterm delivery, hypertensive disorder of pregnancy, preterm premature rupture of membranes, and anemia were more evident in the study group than in the control group. Anemia and placental abruption were seen only in the study group and were completely absent in the control group. (Table 2)

The association between bleeding episodes in the first trimester and adverse maternal outcomes was found to be significant. (p-value 0.001) (Table 2)

Table 2 - Distribution According To Maternal And Neonatal Outcome

		Cases	Control	p-Value
Maternal outcome	Pre-term premature rupture of membranes(PPROM*)	6	2	0.0758
	Anemia	5	0	0.0139
	Hypertensive disorder of pregnancy	9	3	0.0329
	Placental Abruption	2	0	0.1754
	Preterm delivery	11	2	0.0032
	Fetal growth restriction	13	16	0.8357
	No complication	54	77	0.001
Neonatal outcome	Low birth weight	35	21	0.0001
	Premature babies	24	6	0.0001
	Perinatal death	4	0	0.0076
	NICU* Admission	11	5	0.0029
	Full-term live baby	26	68	0.0001

The fetal outcome of a full-term live baby was seen in 68 patients in the control group while it was evident in 26 patients in the study group.

Low birth weight, neonatal intensive care admission of baby, and premature baby as adverse fetal outcomes were seen more in the study group compared to the control group. Perinatal death was seen in only the study group with 4 patients.

The association between adverse fetal outcome and bleeding per vaginum in the first trimester was significant (p-value0.0001) (Table 2) 34 study participants had subchorionic hemorrhage, but only 12 had maternal complications while 28 had neonatal complications, showing a significant association (p-value 0.04) between the presence of subchorionic hemorrhage and poor neonatal outcome. (Table 3)

Table 3 - Distribution Of Pregnancy Outcome In Relation To Subchorionic Hemorrhage In The Study Group.

	Subchorionic Hemorrhage	Present	Absent	p-Value
Maternal outcome	Pre-term premature rupture of membranes	0	6	0.076
	Anemia	1	4	0.639
	Hypertensive disorder of pregnancy	7	2	0.068
	Placental Abruption	0	2	0.514
	Preterm delivery	4	7	1.00
	Fetal growth restriction	0	13	0.003
	No complication	22	32	0.14
Neonatal outcome	Low birth weight	11	22	0.260
	Premature babies	2	7	1.00
	Perinatal death	4	0	0.003
	NICU* Admission	11	11	0.019
	Full-term live baby	6	26	0.04

DISCUSSION:

Our study has found that vaginal bleeding during the first trimester of pregnancy increases the risk of adverse pregnancy outcomes. Our findings are consistent with various studies that have shown a positive association between first-trimester bleeding episodes and adverse pregnancy events like preterm labor[3-8], PROM*[3-8], gestational hypertension[9], antepartum hemorrhage[8-12], fetal growth restriction[13], low birth weight[3-13] and NICU* admission[3-13].

During pregnancy complex genetic, hormonal, cellular, and immunological components must fully interact and integrate for fertilization, implantation, and development of the embryo[14]. Any deviation in these factors may affect the pregnancy in its course.[14]

Our study indicated that women who have bleeding in early pregnancy are at significantly increased risk of PROM* and preterm labor. Prolonged PROM* was also a common indication for LSCS* in the study group. Our study findings are consistent with the prospective observational study carried out by PD Kamble et al[22] in 1007 patients with vaginal bleeding in the first trimester. Preterm delivery is the leading cause of death in normal newborns. Preterm premature rupture of membranes (PPROM*) occurs in up to 40% of preterm deliveries. The causes of the onset of preterm labor and PPROM* in cases of threatened abortion could be disturbance of the chorionic-amniotic plane by nearby bleeding which may render the membranes more prone to rupture.[23] Alternatively, persistent blood may serve as a nidus for intrauterine infection..[24,25]

Our data shows that the incidence of complications like hypertension in pregnancy, antepartum hemorrhage, and perinatal mortality was relatively increased in women who experience bleeding in early pregnancy. Our findings are similar to the prospective case-control study conducted by Jahan Ara et al[26]

Impaired invasion of cytotrophoblast, remodeling of the spiral arteries in early Placentation and oxidative stress could be the link between first-trimester bleeding and complications later in pregnancy like preeclampsia, placental abruption, and fetal growth restriction.[27]

Our study results were comparable to the study conducted by S. Bhandari et al[28], Meenal S. Sarmalkar et al[29], and Shyamala Guruvare et al[30] concerning Preterm labor and PPROM* leading to the low birth weight which increased the rate of NICU* admissions.

Our study findings were similar (Table 3) to the study conducted by Dongol A. et al.[31] Spontaneous abortion was found more in cases with subchorionic hematoma of size more than 20 cm^2. The size, location, and gestational age at SCH* formation are just a few of the specific SCH traits that have been linked to specific outcomes. Large volumes of SCH* have specifically been linked to poor obstetric outcomes, although other research shows that the location of SCH* is more crucial in predicting pregnancy outcomes. [24,25,31,32]

CONCLUSIONS

Our results conclude that the incidence of adverse pregnancy outcomes like pre-term delivery, PPROM*, preeclampsia, antepartum hemorrhage, low birth weight, and increased NICU* admissions is higher in pregnancies complicated by first-trimester bleeding per vaginum.

Strength And Limitations:

- Literature has very few researches studying the outcome of pregnancies with first trimester bleeding with pregnancies that continue beyond the first trimester. We have studied the outcome of pregnancies with BPV* in the first trimester and pregnancies that continued after 13 weeks of gestation .We have found a significant association between BPV* in the first trimester and adverse maternal and neonatal outcomes.
- Since the study was done at a single center with a limited sample size, the results cannot be generalized and warrant the need for a multicentric study with a larger sample size.

Conflict Of Interest: None

Ethical Approval:

The study was approved by the Institutional Ethics Committee, Nowrosjee Wadia Maternity Hospital, and Seth G. S. Medical College, Mumbai.

List Of Abbreviations:

- BPV - Bleeding per Vaginum
- PROM - Premature rupture of membranes
- PPROM - Preterm Premature rupture of membranes
- FGR- Fetal growth restriction
- LBW- Low birth weight
- APH- Antepartum Hemorrhage
- LSCS- Lower segment Caesarean section
- NICU- Neonatal intensive care unit
- SCH- Subchorionic hemorrhages
- NVD- Normal vaginal delivery
- PTVD- Preterm vaginal delivery
- USG- Ultrasonography
- ANC- Antenatal Care
- Sr. TSH- Serum thyroid stimulating Hormone
- FBS- Fasting Blood Sugar
- PLBS- Postprandial Blood Sugar
- NT-NB Scan- Nuchal Translucency- Nasal Bone Scan
- TVS- Trans Vaginal Sonography
- FSB- Fresh Still Birth
- MSB- Macerated Still Birth
- IUFD- Intra-Uterine Fetal Demise
- NND- Neonatal Death
- BMI- Body mass index

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