ISSN: 2581 – 3633
PubMed - National Library of Medicine - ID: 101745081

International Journal of Medical Science and Advanced Clinical Research (IJMACR)

Available Online at: www.ijmacr.com

Volume – 5, Issue – 3, May - June - 2022, Page No. : 26 - 33

Pregnancy outcome after Vaginal Bleeding during First Trimester of the Pregnancy- A Prospective Observational Study

[1]Dr. Pooja Patil, MD, Professor and Head of Department, Department of Obstetrics and Gynaecology, LN Medical College, Bhopal, MP.

[2]Dr. Ankita Shivhare, Junior Resident, Department of Obstetrics and Gynaecology, LN Medical College, Bhopal, MP.

Corresponding Author: Dr. Ankita Shivhare, Junior Resident, Department of Obstetrics and Gynaecology, LN Medical College, Bhopal, MP.

How to citation this article: Dr. Pooja Patil, Dr. Ankita Shivhare, "Pregnancy outcome after Vaginal Bleeding during First Trimester of the Pregnancy- A Prospective Observational Study", IJMACR- May - June - 2022, Vol – 5, Issue - 3, P. No. 26 – 33.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Background: Vaginal bleeding during the first trimester of the pregnancy is a serious complication affecting about one in four pregnancies. The outcome of such a pregnancy is determined by the cause, timing, and amount of the bleeding.

AIM: To determine the incidence of adverse maternal outcomes among pregnant women diagnosed with vaginal bleeding during the first trimester. **Material & Methods:** This was a single centre, open, prospective, cohort study. A total of 110 women were enrolled in the present study. Data on obstetric history, duration-, timing-, and pattern of bleeding were collected.

Results: Of the total 110 enrolled women, 10 women were lost to follow and the data on outcome was available for only 100 pregnant women. The most common diagnosis of vaginal bleeding was threatened abortion (70%) followed by missed and complete abortion (9% each). For about 30% of women, the pregnancy ended in the form of 1st-trimester abortion. Further, among 70 women whose pregnancy continued beyond the first trimester, only 30% of women did not have any complications during the pregnancy (had uneventful full-term labour), and 17.4% of participants had pre-term labour. Out Of the 69 pregnant women whose pregnancy continued beyond 24 weeks, about 29% of neonates were born pre-term, about 23% of new-born had IUGR and >50% of children had birth weight> 2500 grams.

Conclusion: Vaginal bleeding during the first trimester endangers the continuation of pregnancy. The most common diagnosis of vaginal bleeding in the first trimester was threatened abortion and the most common adverse outcome was preterm delivery.

Keywords: First trimester, vaginal bleeding, maternal, foetal

Introduction

Gradually, over the last several decades it has become easier to manage the complications of late pregnancy because of the widespread availability of facilities offering emergency caesarean section and new born resuscitation[1]–[3]. However, every stage of pregnancy from conception to labour (and even the postpartum period) is marked by a myriad of complications that can endanger either the life of the mother or her unborn child[4]. Thus, the fate of the pregnant woman (and her unborn child) depends on the timing, type, and severity of the complications [5]. Furthermore, some pathological conditions have both immediate and delayed complications[5].

Therefore, the focus has now been shifted to the complications predominantly encountered during the first and second trimester of pregnancy that can result in adverse maternal and foetal outcome(s)[6]. Vaginal bleeding during the first trimester is both a common and a serious complication. Medical records suggest that one in four pregnant women have varying degrees of vaginal bleeding during the first trimester[5]. However, not all incidents of vaginal bleeding result in adverse maternal outcomes. There are several causes of vaginal bleeding during the first trimester; some conditions are self-limiting while others are progressive[6], [7]. Further, some conditions resolve spontaneously with minimal intervention whereas others require hospital admission. A significant proportion of women have a spontaneous abortion within a few weeks from the start of vaginal bleeding during the first trimester[8]. Even if the vaginal bleeding during the first trimester is self-limiting that resolves spontaneously without causing any harm to the growing foetus it can nevertheless cause severe anxiety to the pregnant women (and other family members) resulting in restricted physical activity including temporary leave from the job[4]. Therefore, every single case of vaginal bleeding needs careful investigation and scrutiny by a qualified medical professional.

The outcome of ongoing pregnancies after first-trimester bleeding is of relevance to women and obstetricians for planning antenatal care and clinical interventions in pregnancy[9]. Invitro studies suggest that vaginal bleeding and consequent thrombin generation lead to a proteolytic cascade capable of damaging the foetal membranes and stimulating uterine contractions, which could result in preterm premature rupture of the membranes and preterm labour[10]. Local haemostatic factors in the uterus during implantation, decidualization, early pregnancy, and systemic factors in the women during the ongoing pregnancy seem to play distinct roles in a successful pregnancy outcome[10]. Local formation of thrombin and soluble forms-like tyrosine kinase-1 seem to be involved in the development of placental abruption and preeclampsia. Several researchers have proposed that first-trimester vaginal bleeding is a marker of a general proclivity to other pregnancy complications surfacing later in the pregnancy[9], [10].

However, the scientific literature regarding threatened abortion is relatively limited for outcomes besides viability at term[11], [12]. Further, most of the studies evaluating the outcome of vaginal bleeding in the first trimester were retrospective studies, therefore recall bias may influence the validity of findings from these studies. Lastly, most of the studies that determine the outcome among pregnant women with first-trimester abortion

were conducted in developed countries[13], [14]. Therefore, we conducted this prospective observational study to measure the incidence of various adverse outcomes among pregnant women with vaginal bleeding during the first trimester of pregnancy.

Material & methods

A single centre, open, prospective, cohort, observational study was done in the Department of Obstetrics & Gynaecology, for a total of 21 months; from December 2019 to August 2021. The participants were recruited into the study after verifying that they fulfilled the following criteria:

Inclusion

- Pregnant women presenting with bleeding per vaginum in the first trimester
- Patients agreeing to provide written informed consent.

Exclusion Criteria

- Patient with ectopic pregnancy
- Patients on anticoagulants therapy
- Patients who have taken abortifacients drugs
- A patient who refused to take part in the study.

Study Outcomes: (i) Any of the following adverse maternal outcomes:

a. Abortion
b. Antepartum haemorrhage
c. Development of liquor abnormalities,
d. Premature Rupture of Membrane,
e. Preterm labour pains and delivery,
f. Pregnancy Induced Hypertension.

End Point of Study

(i) A participant decided to withdraw from the study.

(ii) After the end of the pregnancy irrespective of the outcome of pregnancy.

Sample Size

The smallest required sample size for the study was estimated following the recommendation of Charan et al (2012) for a cohort study[15]. Using the prescribed formula, the minimum sample size was calculated as ninety-seven.

Sampling Methodology

we employed the non-random, purposive, convenience sampling methodology to recruit participants for the study. Pregnant women coming to the emergency/outpatient department with complaints of vaginal bleeding were managed as per the recommended protocol. After providing the recommended care to the patient, the prospective participants were approached for informed consent. The principal investigators approached all prospective participants and explained to them in detail the study procedure and participants' roles (and implications).

Informed Consent

A bilingual (Hindi, & English) consent form was drafted following the prescribed guidelines for research on human participants. The consent form was given to all the participants to read. Thereafter, the contents of the consent form were explained to all the prospective participants. The participants were informed and explained that they have the right to withdraw from the study at any point in time. Thereafter, willing participants were asked to sign the consent form.

Data Collection

The data were collected in a paper-based form. The form had 4 parts as follows

(i) Demographic details

(ii) Pregnancy and Obstetrics history

(iii) Clinical Examination and Laboratory Investigations (iv) Follow up. Predictor variables for the present study included: onset, duration, pattern, and

quantity of bleeding during the first trimester and ultrasonography findings.

Source of Data

There were three sources of data. The first source was the questionnaire-based interview with the participant; the second source was the clinical records of the participants, and the last source of data was the laboratory and radiological reports of the participants.

Follow up

The participants were followed up as per ANC protocols and as per the requirements according to the developed complications until the outcome event. The follow up was conducted either at the Outpatient Clinic (OPD) or telephonically.

Statistical Analysis Plan

The primary outcome was the incidence of adverse maternal events/outcomes (see above) among the study participants. The coded data were imported into Stata 16.1 version for analysis. For the continuous data, the authors calculated the mean, median, mode, standard deviation, and inter-quartile range. For discrete data, we calculated and reported frequency, proportion, and percentage. We followed the scientific convection for detecting a significant difference between two groups of P-value < 0.05 [16].

Results

To recruit participants for the present study, we approached a total of 134 women who reported vaginal bleeding during the first trimester: 17 (12.7%) women were excluded, 7 (5.2%) women refused to participate, and the remaining 110 (82.1%) women were enrolled on the study. Further, 10 women were lost to follow up and therefore the data on outcome was available for only 100 participants. The mean and the median age of the participants were 24.8 (±2.9) and 26 years. The minimum and the maximum age of women ranged from 18 to 31 years. The mean period of gestation at the time of vaginal bleeding was 10 weeks. Most women (36%) were gravida 2, 30% were primigravida followed by 22% who were gravida 3.

Table 1 gives the detail of the final diagnosis/cause of vaginal bleeding among the participants. The most common diagnosis of vaginal bleeding among the participants was threatened abortion (70%) followed by missed and complete abortion (9% each). The two least common diagnoses were inevitable abortion and blighted ovum (2% each).

Table 1: Diagnosis of First Trimester Vaginal bleeding among participants (n=100)

Diagnosis	n	%
Threatened abortion	70	70.0
Missed Abortion	9	9.0
Incomplete Abortion	5	5.0
Complete Abortion	9	9.0
Inevitable abortion	2	2.0
Blighted Ovum	2	2.0
Molar Pregnancy	3	3.0

Of the total 100 pregnant women enrolled in the study, 30 participants had 1st-trimester abortions. There was no significant difference between the mean age of participants who had first-trimester abortion (23.4 years) and those whose pregnancy continued beyond the first trimester (25.6 years) (p>0.05). Table 2 shows the outcome among 70 study participants whose pregnancy continued beyond the first trimester. A total of 30.0% of women did not have any complications during the pregnancy and had uneventful full-term labour and 70% had some or other complications (see table 2 for details). Hypertensive disorders of pregnancy were seen in 14.3%

of total participants. Second-trimester abortion was seen in only one participant.

Table 2: Outcome among study participants (n=70)

Diagnosis	n	%
No complications	21	30.0
2nd Trimester Abortion	1	1.4
Preterm Labour	12	17.4
PROM	9	12.8
PPROM	7	10.0
Placenta Previa	6	8.5
Abruptio Placenta	2	2.8
Severe Pre-eclampsia	4	5.8
PIH	6	8.5
Oligohydramnios	2	2.8

Table 3 shows the gestational age at the time of outcome among study participants. Out of seventy women who had a continuation of pregnancy beyond the first trimester, twenty-five women had preterm delivery (35.7%), Out of which only one was extremely preterm (24-27 weeks) secondary to antepartum haemorrhage.

Table 3: Gestational Age at Delivery (n=70)

Gestation Age (weeks)	n	%
<24 (2nd trimester abortion)	1	1.4
24-27	1	1.4
28-31	2	2.8
32-37	22	31.6
>37	44	62.8
Total	70	100.0

Figure 1: Gestational age at delivery (n=70)

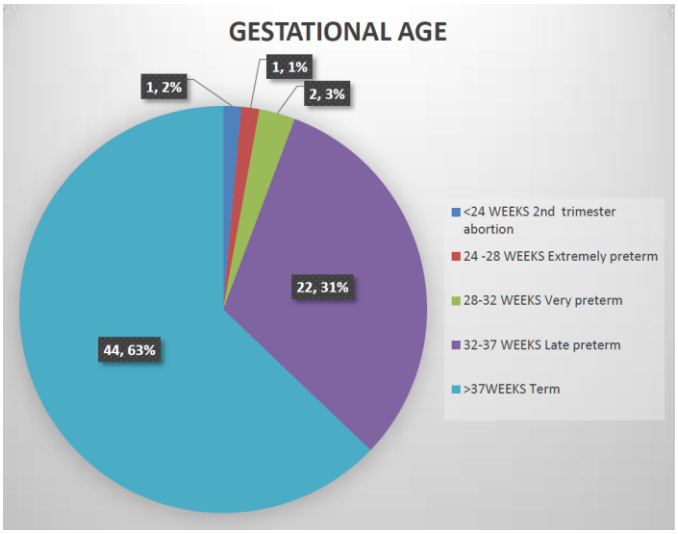

Table 4 shows the outcome of pregnancies that continued beyond 24 weeks of gestation. Of the total 69 women whose pregnancy continued beyond 24 weeks of gestation, 43.5% of women delivered a full-term healthy new born, 29% women had a preterm neonate, and 23.2% women gave birth to a child with IUGR. The mean birth weight of the new born is 2791 (±325) grams. Also, more than 50% of new-born had a weight >2500 grams.

Table 4: Foetal Outcome (n=69)

	n	%
Foetal Outcome (n=69)		
Full Term Normal	30	43.5
IUFD/Stillbirth	3	4.3
IUGR	16	23.2
Preterm	20	29.0

Discussion

The majority (70%) of the women with vaginal bleeding were diagnosed as threatened abortion followed by complete abortion and missed abortion (9% each). Other less common diagnoses were incomplete abortion (5%), molar pregnancy (3%), inevitable abortion (2%), and blighted ovum (2%). A similar study conducted by Patel

NG et al. (2014) reported that among their study population 45% had single live intrauterine foetus, 24% had threatened abortion, 8% had an ectopic pregnancy, 7% had missed abortion, 5% had a vesicular mole, 3% had blighted ovum, and 2% each had an inevitable abortion, incomplete abortion, twin gestation and anencephaly[17].

As the major risk associated with threatened abortion is loss of pregnancy. A total of 30 women had a spontaneous abortion in the 1st trimester even after all supportive treatment and one woman had an abortion in the 2nd trimester. Thus 70% of women had a continuation of pregnancy beyond 12 weeks and amongst them also 30% developed one or the other complications. The most found complications in this group were preterm labour (17.4%), PROM (12.8%) and PPROM (10%)., Others were placenta previa (8.5%), abruptio placentae (2.8%), and Oligohydramnios (2.8%). In 2012 Ahmed RS et al and Sarmalkar MS et al. 2017 also reported a significantly increased incidence of pre-term delivery, low birth weight babies, and premature rupture of membranes among participants with threatened abortion compared to the control group[18], [19]. Thus, women with threatened abortion in 1st trimester may be at increased risk of having a preterm delivery.

The overall rate of preterm delivery was 35.7%, out of which 14% delivered prematurely due to hypertensive disorders of pregnancy of which gestational hypertension and pre-eclampsia were seen among 8% and 6% respectively. The majority 22.3% of preterm deliveries were late preterm deliveries i.e., between 32-37 weeks and only one (1.2%) had extremely preterm delivery (less than 28 weeks) due to APH. Rashmi et al 2020 observed a very low incidence of term delivery (4.5%) in their study on women with threatened abortion, 56.8% had a late preterm delivery, 25% had very pre-term and 13.7% had extremely pre-term delivery[20]

FGR/ IUGR is a commonly diagnosed complication due to better ultrasound facilities. Amongst women who continued pregnancy beyond the first trimester, sixteen women (23.2%) had developed FGR foetus, and 3 (4.3%) women presented with IUFD. Though the causes of having asymmetrical IUGR are multiple, hypertensive disorders of pregnancy are also one of the known risk factors. Further studies are required to establish the co-relation between threatened abortion in the first trimester, HDP and IUGR. Dongol A et al. (2011) reported a comparatively lower incidence of IUGR (13.2%) among the pregnancies that continued after a first trimester threatened abortion[21]. They also report that the incidence of IUD was 5.6% in their study[21]. Foetal growth restriction is also seen in women with threatened abortions. Different studies have noted it but whether it's more in women with threatened abortion needs more clarification with research with the control group [22]. In some studies, perinatal death has also been found amongst women with first-trimester threatened abortion as Amirkhani Z et al (2013) reported that the perinatal death was observed among 6.5% of participants with a history of first-trimester threatened abortion[13].

Conclusion

First trimester vaginal bleeding adversely affects both the maternal and foetal outcomes. Very few pregnant women who experience vaginal bleeding during the first trimester have an uneventful maternal and foetal outcome. Pregnant women who experience vaginal bleeding during the first trimester are at increased risk of various complications at every stage of pregnancy. Thus,

women with the first trimester threatened abortion must be kept under surveillance throughout their antenatal period keeping all these complications in mind and women must also be educated about the need for proper follow-up and antenatal care throughout their pregnancy for early detection of complications and respective management.

Funding

There was no funding for the present study. The participants were not paid any type of fees/incentives/freebees to participate in the study.

Conflict of Interest: The author(s) declares that he/she/they has/have no competing interests.

References

1. Z. Ou et al., "Global trends in incidence and death of neonatal disorders and its specific causes in 204 countries/territories during 1990–2019," BMC Public Health, vol. 22, no. 1, Dec. 2022, doi: 10.1186/S12889-022-12765-1.

2. D. Vidyasagar, "Global issues in perinatal medicine," Semin. Fetal Neonatal Med., vol. 20, no. 5, pp. 283–284, 2015, doi: 10.1016/j.siny.2015.08.001.

3. M. F. Gaffey, J. K. Das, and Z. A. Bhutta, "Millennium Development Goals 4 and 5: Past and future progress," Semin. Fetal Neonatal Med., vol. 20, no. 5, pp. 285–292, Oct. 2015, doi: 10. 1016/ J.SINY. 2015. 07. 001.

4. A. Olugbenga, "Pregnancy outcome in women with early pregnancy bleeding in a tertiary health care facility in Southwestern, Nigeria," J. Mahatma Gandhi Inst. Med. Sci., vol. 24, no. 2, p. 87, 2019, doi: 10.4103/jmgims.jmgims_29_16.

5. L. Saraswat, S. Bhattacharya, A. Maheshwari, and S. Bhattacharya, "Maternal and perinatal outcome in women with threatened miscarriage in the first trimester: a systematic review," BJOG An Int. J. Obstet. Gynaecol., vol. 117, no. 3, pp. 245–257, Feb. 2010, doi: 10.1111/J.1471-0528.2009.02427.X.

6. I. Szymusik, P. Bartnik, K. Wypych, H. Kolaczkowska, K. Kosinska-Kaczynska, and M. Wielgos, "The association of first trimester bleeding with preterm delivery," J. Perinat. Med., vol. 43, no. 5, pp. 525–529, Sep. 2015, Accessed: Apr. 27, 2022. [Online]. Available: https:// www. degruyter. com/ document/ doi/ 10.1515 /jpm-2015- 0063/html.

7. C. J. Lockwood, "Risk factors for preterm birth and new approaches to its early diagnosis," J. Perinat. Med., vol. 43, no. 5, pp. 499–501, Sep. 2015, doi: 10.1515/JPM-2015-0261/HTML.

8. G. Maiti, P. Ibgnait, A. Pillai, and V. Shukla, "Maternal and perinatal outcome in women with threatened miscarriage in the first trimester," J. Mar. Med. Soc., vol. 15, no. 2, p. 98, 2022, doi: 10.4103/0975-3605.203317.

9. L. L. Jelliffe-Pawlowski et al., "Maternal characteristics and mid-pregnancy serum biomarkers as risk factors for subtypes of preterm birth," BJOG An Int. J. Obstet. Gynaecol., vol. 122, no. 11, pp. 1484–1493, Oct. 2015, doi: 10.1111/1471-0528.13495.

10. M. Hadzi-Lega, A. D. Markova, M. Stefanovic, and M. Tanturovski, "Correlation of cervical length, fetal fibronectin, phIGFBP-1, and cytokines in spontaneous preterm birth up to 14 days from sampling," J. Perinat. Med., vol. 43, no. 5, pp. 545–551, Sep. 2015, doi: 10.1515/JPM-2014-0275/HTML.

11. B. Yakıştıran, T. Yüce, and F. Söylemez, "First trimester bleeding and pregnancy outcomes: Case-control study," Int. J. Women's Heal. Reprod. Sci., vol. 4, no. 1, pp. 4–7, 2016, doi: 10.15296/ijwhr.2016.02.

12. J. A. Lykke, K. L. Dideriksen, Ø. Lidegaard, and

J. Langhoff-Roos, "First-trimester vaginal bleeding and complications later in pregnancy," Obstet. Gynecol. Surv., vol. 65, no. 9, pp. 563–564, 2010, doi: 10.1097/OGX.0b013e3182021d8d.

13. Z. Amirkhani et al., "Maternal and Perinatal Outcomes in Pregnant Women with First Trimester Vaginal Bleeding," J. Fam. Reprod. Heal., vol. 7, no. 2, p. 57, Jun. 2013, Accessed: Apr. 24, 2022. [Online]. Available: /pmc/articles/PMC4064773/.

14. L. Sun, F. Tao, J. Hao, P. Su, F. Liu, and R. Xu, "First trimester vaginal bleeding and adverse pregnancy outcomes among Chinese women: From a large cohort study in China," J. Matern. Neonatal Med., vol. 25, no. 8, pp. 1297–1301, Aug. 2012, doi: 10.3109/ 14767058. 2011. 632034.

15. B. Zhong, "How to Calculate Sample Size in Randomized Controlled Trial?," J. Thorac. Dis., vol. 1, no. 1, p. 51, 2009, Accessed: Dec. 01, 2021. [Online]. Available: /pmc/articles/PMC3256489/.

16. "How to Choose Statistical Tests in Medical and Pharmacy Research? | Pothi.com." https:// store. pothi. com /book/ ebook- dr- jaykaran- charan-how-choose-statistical-tests-medical-and-pharmacy-research/ (accessed Dec. 13, 2021).

17. N. Patel, M. Patel, S. Shah, S. Jani, J. Patel, and J. Shah, "Study of outcome of pregnancy in patients with first-trimester bleeding per vaginum," Int. J. Adv. Med., vol. 1, no. 3, p. 230, 2014, doi: 10.5455 /2349-3933 .ijam20141111.

18. S. R. Ahmed, M. E.-K. El-Sammani, M. A.-A. Al-Sheeha, A. S. Aitallah, F. J. Khan, and S. R. Ahmed, "Pregnancy Outcome in Women with Threatened Miscarriage: a Year Study," Mater. Sociomed., vol. 24, no. 1, p. 26, 2012, doi: 10.5455/MSM.2012.24.26-28.

19. M. S. Sarmalkar, S. Singh, and A. H. Nayak, "Maternal and perinatal outcome in women with threatened abortion in first trimester," Int. J. Reprod. Contraception, Obstet. Gynecol., vol. 5, no. 5, pp. 1438–1445, Jan. 2017, doi: 10. 18203/ 2320- 1770. IJRCOG 20161301.

20. Rashmi, A. Gs, and Radhika, "Prospective study of pregnancy outcome in patients with first trimester bleed in a tertiary centre," ~ 22 ~ Int. J. Clin. Obstet. Gynaecol., vol. 4, no. 3, pp. 22–25, 2020, doi: 10.33545/gynae.2020.v4.i3a.570.

21. A. Dongol, S. Mool, and P. Tiwari, "Outcome of pregnancy complicated by threatened abortion," Kathmandu Univ. Med. J. (KUMJ), vol. 9, no. 33, pp. 41–44, 2011, doi: 10.3126/ KUMJ.V9I1.6261.

22. A. Wijesiriwardana, S. S. Bhattacharya, A. Shetty, N. Smith, and S. S. Bhattacharya, "Obstetric outcome in women with threatened miscarriage in the first trimester," Obstet. Gynecol., vol. 107, no. 3, pp. 557–562, Mar. 2006, doi: 10.1097 /01. AOG. 0000 199952. 82151.de.