



Assessment of Maternal and Perinatal Outcomes among Pregnant Women with First-Trimester Vaginal Bleeding

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ABSTRACT

First-trimester vaginal bleeding predicts future maternal and fetal complications. But, these studies have been explored to a lesser extent, especially from western India. This is a single-centred prospective observational study of pregnant women with vaginal bleeding in the first trimester (<12 weeks of gestation) conducted over 18 months. Consecutive pregnant women were included by convenience sampling. Patients were followed up till delivery to study perinatal outcomes. Sixty-nine pregnant women with a Mean \pm SD age of 24.4 \pm 4.8 years, most 48 (69.6%) aged between 20-29 years were included. Majority received above primary schooling 52 (75.4%), had a lower middle socioeconomic status 32 (46.4%), were unemployed/housewives 39 (56.5%) and 37 (53.6%) were primigravida. The type of bleeding was spotting in 35 (50.7%) patients and pregnancy could be continued in 47 (68.1%) patients. Unfortunately, 22 (31.9%) patients underwent termination in the first trimester: 39 (56.5%) and 8 (11.6%) had unfavourable and favourable outcomes, respectively. The most common complication was preterm labour in 12 (17.4%), followed by preterm premature rupture of membranes in 9 (13%) patients. The commonest neonatal complication was preterm delivery in 23/47 (48.9%), requiring NICU admission, followed by IUGR in 8/47 (17%). No significant association was seen between age, literacy/socioeconomic status, occupation and pregnancy outcome. An increased proportion of favourable pregnancy outcomes was seen in deliveries at 37-42 weeks ($p<0.001$). Pregnant women presenting with first-trimester vaginal bleeding are at high risk for loss of pregnancy and adverse outcomes in terms of preterm birth and need for NICU care. Pregnancy loss needs future attention in pregnancy planning. All pregnant women should be counselled regarding such complications and the need for emergency medical care.

INTRODUCTION

Vaginal bleeding is common in the first half of pregnancy^[1]. First-trimester bleeding is an ominous sign presenting as a threat to the embryo and a source of anxiety to the expectant mother. It usually results from disrupting blood vessels in the decidua or a discrete cervical or vaginal lesion^[2]. Vaginal Bleed during the first trimester has been estimated to occur in 16-25% of all pregnant women^[3,4]. About one-half of those who bleed will miscarry. A provisional clinical diagnosis is based on the gestational age and the character of bleeding (e.g., spotting, light or heavy flow, intermittent or constant, associated with pain or painlessness)^[5]. Physical examination and laboratory and/or imaging tests are then used to support or revise the initial diagnosis^[6]. Bleeding can be associated with an adverse pregnancy outcome or an ectopic pregnancy, which can be life-threatening^[7].

Meta-analysis indicates that vaginal bleeding is associated with a two-fold increased risk of other complications during pregnancy^[8]. Further, it is hypothesized that first-trimester bleeding may indicate an underlying placental dysfunction, manifesting as an increased risk of pre-eclamptic toxemias, preterm delivery, premature rupture of membranes (PROM) and IUGR^[9]. The outcomes of ongoing pregnancies after first-trimester bleeding are relevant to women and obstetricians for planning future antenatal care and clinical interventions. The prognosis of threatened abortion is very unpredictable, whatever treatment method is employed in a hospital or home. Several studies tried identifying adverse fetal outcomes but few have explored maternal complications. The present prospective study investigates the relationship between vaginal bleeding in the first trimester and selected adverse-perinatal outcomes in singleton pregnancies in Indian patients. We also aim to study maternal as well as perinatal complications so that there is a reduction in morbidity and mortality.

MATERIALS AND METHODS

This is a single-centred prospective observational study of pregnant women with vaginal bleeding in the first trimester (<12 weeks of gestation) conducted over 18 months in the Department of Obstetrics and Gynecology of a tertiary care teaching hospital in India. Patients were followed up till delivery to study perinatal outcomes. Ethical approval was obtained from the Institutional ethics committee before the start of the study. Data privacy and confidentiality were maintained throughout the study. Patients were approached and briefed regarding the study procedure and those who gave consent to participate in the study by signing the informed consent form (ICF) were given a photocopy of the signed ICF about the research study for their records. The patients were then examined and

their relevant clinical history was collected per the case record form. This study was conducted in accordance with Good Clinical Practice and to conform to the Helsinki Declaration of 1975, as revised in 2013, concerning human rights.

Inclusion criteria included the following: positive pregnancy test, amenorrhea < 3 months, normal body mass index, reliable date of last menstrual period, first trimester (<12 weeks) and bleeding P/V in the first trimester only. Exclusion criteria included mothers with more than 12 completed weeks of gestation, women with past comorbid illnesses (Diabetes mellitus, Hypertension, Bleeding disorders), all non-obstetrical causes of vaginal bleeding and multiple pregnancies.

A detailed history and examination were made at admission and follow-up visits were taken throughout the pregnancy. Data from all these detailed histories and examinations were compiled to reflect all trimester information. The amount of bleeding was noted. If simply spotting, it was considered as light. If similar to patient's menstrual bleeding or more, it was considered as heavy. When a miscarriage occurred before a scheduled follow-up visit, the history and examination were done immediately after pregnancy loss. The nonviability of pregnancy was confirmed by USG and terminated based on the institution's protocol. Patients with ectopic underwent further definitive treatment. Patients with molar gestation underwent suction and evacuation. All Rh-negative women with 1st trimester bleeding were offered Injection anti-D antibody. Patients with viable pregnancies were followed up with regular antenatal checkups. Viable pregnancies were advised to rest adequately, micronized progesterone vaginally or orally and one follow-up USG after 10-15 days. Outcome data were collected from hospital notes, regular ANC, telephone interviews and follow-up examinations and investigations. Post-delivery follow-up was performed by telephone interview or medical record review.

Patients were admitted to the hospital as and when necessary. The outcome data obtained from the hospital notes were confirmed by telephone follow-up wherever needed. The fetal outcome of pregnancy was categorized as:

- Non-viable outcome (termination of pregnancy before 20 weeks):
 - Spontaneous or induced termination
 - Congenital malformations that were terminated before 20 weeks
- Viable outcome (continuation of pregnancy after 20 weeks)
 - Preterm delivery
 - Low birth rate (<2.5 kg)
 - Intrauterine growth retardation
 - Perinatal death

- Neonatal intensive care unit (NICU) admission
- Full-term live birth with a healthy fetus

Terminated and unfavourable cases were grouped together to find associations between the favourable maternal outcome and study variables. All patients were managed as per appropriate guidelines.

Sample size and statistical analysis: Using an anticipated sensitivity for Ultrasound abdomen for normal pregnancy based on a pilot study of 100 cases of vaginal bleeding in 1st trimester pregnancy = 97.67%, an absolute precision of 8% and considering a confidence level of 95%, the Minimum calculated sample size was 69. Consecutive pregnant women were included by convenience sampling.

All statistical analyses were performed using SPSS 26.0 statistics software (SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were used, mean and range were given as appropriate for quantitative variables. Categorical variables were reported as frequencies and percentages. The Chi-square test was used for nonparametric nominal data. A $p < 0.05$ was considered significant.

RESULTS

Sixty-nine pregnant women with a mean \pm SD age of 24.4 ± 4.8 years, most 48 (69.6%) aged between 20-29 years were included. The most common age group in the study population was 20-24 years 38 (55.1%), followed by 10 (14.5%) in 25-29 years (Fig. 1). The lowest proportion, 4 (5.8%) of patients, belonged to the age group ≥ 35 years. Most patients, 32 (46.4%), belonged to lower middle socioeconomic status based on the socioeconomic scale. The majority received above primary schooling 52 (75.4%). The most common occupation in the study population was Unemployed/housewives 39 (56.5%), followed by working mothers 27 (39.1%) and students 3 (4.3%).

Most were 37 (53.6%) primigravida, 28 (40.6%) were para 1 and 4 (5.8%) were para 2 and above. Almost one quarter, 17 (24.6%) of study participants, had a history of previous abortions (Table 1).

Clinical outcomes: Most of the patients in the study population had spotting 35 (50.7%), followed by light bleeding 28 (40.6%). Heavy bleeding was seen in only 6 (8.7%) women, according to self-reporting (Fig. 2). 47 (68.1%) patients could carry the pregnancy beyond the first trimester. However, 22 (31.9%) patients underwent termination of pregnancy/spontaneous abortion in the first trimester.

Of patients who continued pregnancy ($n = 47$) beyond 12 weeks, 31 (44.9%) had a vaginal delivery, 16 (23.2%) underwent caesarean section and 22 (31.9%) patients who underwent first trimester termination were done through suction and evacuation (Fig. 3). Of the 47 patients, 39 had unfavourable outcomes (56.5%) and 8 (11.6%) had favourable results (Fig. 4).

Table 1: Baseline characteristics of patients

Variables	N = 69, n (%)
Mean age \pm SD (years)	24.4 \pm 4.8
Range	19-36
Age group (years)	
<20	7 (10.1)
20-24	38 (55.1)
25-29	10 (14.5)
30-34	10 (14.5)
≥ 35	4 (5.8)
Socio-economic status	
Lower	5 (7.2)
Lower middle	32 (46.4)
Upper	2 (2.9)
Upper lower	17 (24.6)
Upper middle	13 (18.8)
Occupation	
Student	3 (4.3)
Unemployed/housewives	39 (56.5)
Working	27 (39.1)
Parity	
0	37 (53.6)
1	28 (40.6)
2	4 (5.8)
Past history of abortion	
No	52 (75.4)
Yes	17 (24.6)

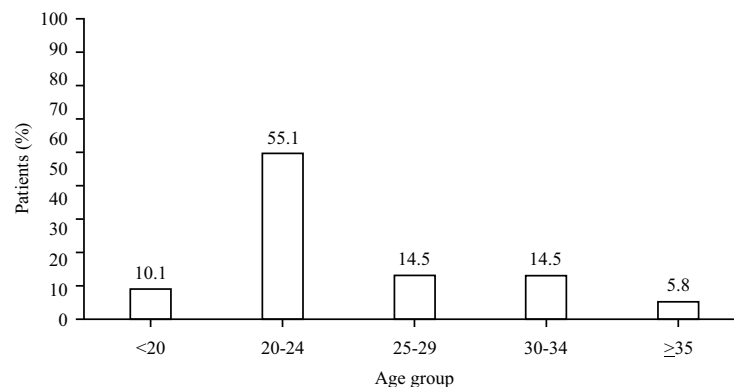


Fig. 1: Distribution of patients based on the age group

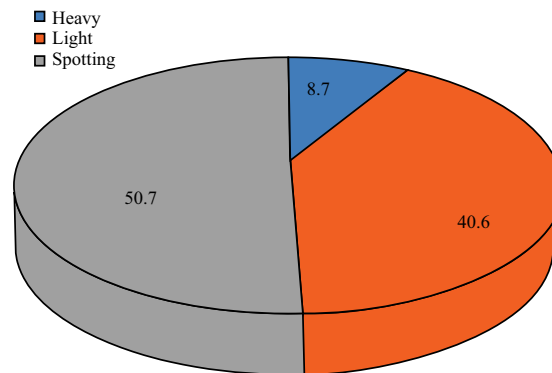


Fig. 2: Distribution of patients based on the type of bleeding

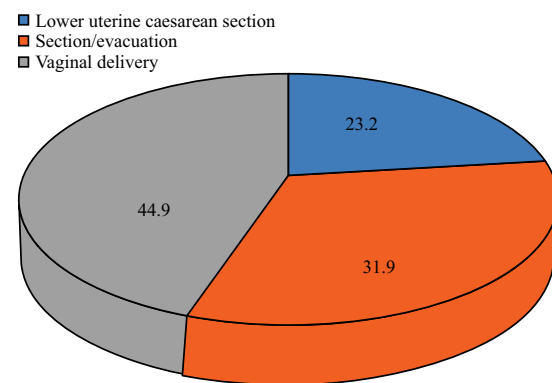


Fig. 3: Distribution of patients based on the mode of delivery

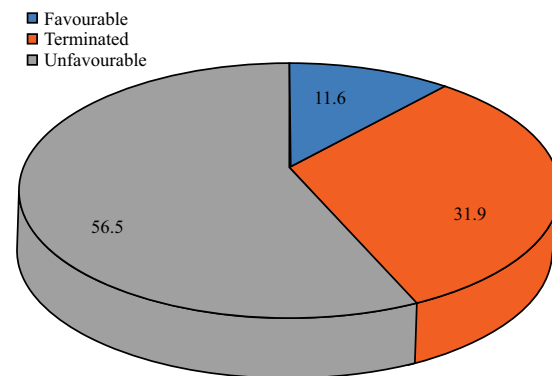


Fig. 4: Distribution of patients based on pregnancy outcome

Out of 47 patients, three patients had second-trimester abortions. The most common complication noted in the continued group was preterm labour 12 (17%) followed by preterm premature rupture of membranes 9 (13%), 1 (1.4%) incident of Intrauterine fetal death was noted in the continual group. Most mothers delivered babies with a normal birth weight of 20 (29%), followed by extremely LBW (ELBW) in 13 (18.8%). Low birth weight (LBW) in 10 (14.5%) and very low birth weight (VLBW) infants in 4 (5.8%) of cases. Approximately one-third 22 (31.9%) of the

pregnancies were terminated, 21 (30.4%) had APGAR scores (5 min) ≥ 7 , while 26 (37.7%) of the infants had APGAR score of < 7 (Table 2).

The commonest neonatal complication was preterm delivery in 23/47 (48.9%), requiring NICU admission, followed by IUGR in 8/47 (17%) (Fig. 5). No significant association was seen between the occupation of the study participants and the pregnancy outcome ($p = 0.08$). No significant association was seen between the amount of bleeding and the pregnancy outcome of the study population ($p = 0.061$). No

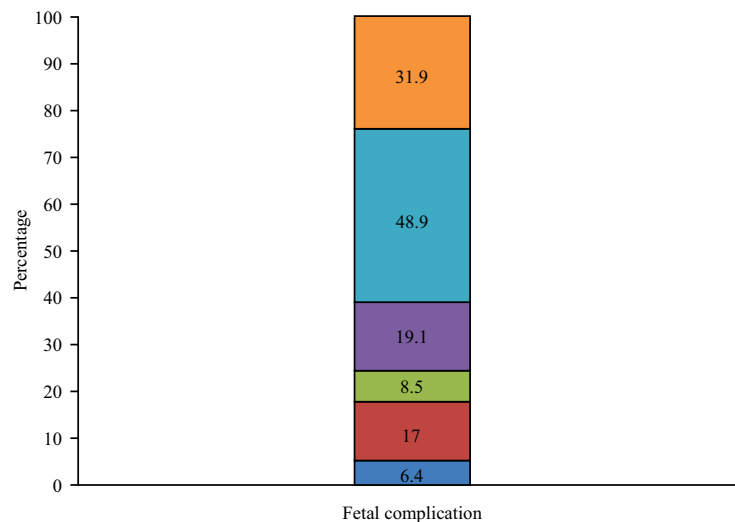


Fig. 5: Staggered bar graph of fetal/neonatal complications

Table 2: Clinical characteristics and outcome of patients with first trimester vaginal bleeding

Variables	N = 69, n (%)
Type of bleeding	
Heavy	6 (8.7)
Light	28 (40.6)
Spotting	35 (50.7)
Pregnancy status	
Continuing	47 (68.1)
Terminated/spontaneous abortion	22 (31.9)
Mode of delivery	
Forceps	1 (1.4)
Lower uterine caesarean section	16 (23.2)
Suction/evacuation	22 (31.9)
Vaginal delivery	30 (43.5)
Pregnancy outcome	
Favourable	8 (11.6)
Terminated	22 (31.9)
Unfavourable	39 (56.5)
Maternal complication	
Aborted	19 (27.5)
APH	2 (2.9)
Hydatidiform mole	2 (2.9)
II trimester abortion	3 (4.3)
IUFD	1 (1.4)
No complication	8 (11.6)
Oligohydramnios	5 (7.2)
PIH	4 (5.8)
PPH	4 (5.8)
Pre-term	12 (17.4)
PROM	9 (13.0)
Baby birth weight	
ELBW (2500 g)	20 (29)
LBW (<2500 g)	10 (14.5)
Normal (>2500 g)	20 (29)
VLBW (<1500 g)	4 (5.8)
Neonatal/fetal complications (n = 47)	
Second trimester abortion	3 (6.4)
IUGR	8 (17.0)
LBW	4 (8.5)
Normal	9 (19.1)
Preterm	23 (48.9)
APGAR score at 5 min (n = 47)	
<7	26 (37.7)
≥7	21 (30.4)

significant association was seen between patients with a history of abortion and the pregnancy outcome ($p = 0.98$). No significant association was seen between

the quantity of bleeding and the viability of the fetus ($p = 0.54$). Out of 69 patients, 17 had a history of abortion. Of 17 patients, 10 had nonviable pregnancies and 7 had viable pregnancies. Rest, 52 patients had no history of previous abortion, out of which 25 were nonviable and 27 were viable outcomes. There is an increased chance of NICU admission of infants born to very low and very high age groups of mothers (71.4% in mothers <20 years and 100% in mothers ≥ 35 years, compared to mothers in the 20-24 year age group (39.5%) and 25-29 years (40%). Out of 47 patients beyond 12 weeks, 3 had second-trimester abortion, rest 44 delivered, out of which 34 infants required NICU care.

DISCUSSIONS

By prospectively following up patients over 18 months, we studied maternal and perinatal outcomes among pregnant women with first-trimester vaginal bleeding. Bleeding during first trimester has been seen to be associated with an increased risk of preterm delivery^[10]. Because of impaired implantation and invasive trophoblasts, spontaneous abortion may occur in early pregnancy while preterm delivery, PPROM, placental abruption, preeclampsia may happen in later period.

The most common age group in the study population was 20-29 years in 48 (69.6%) women. In their study on 1007 mothers with first trimester bleeding from Maharashtra, Kamble *et al.*^[11] reported 21-30 years as the commonest age group in their study cohort. In Karnataka, Hassan *et al.*^[12] reported that 70% of their study population were in the age group 21-30 years and perhaps the reason is that majority of delivery also occur in this age group. Our results are comparable to those seen across India and abroad.

In the present study, most of the patients in the study population had spotting (50.7%). Heavy bleeding was seen in only 8.7% of the study participants, lower than that reported by Kamble *et al.*^[11] (83.2%) and Hasan *et al.*^[13] (75.6%). Hassan *et al.*^[12] reported spotting in only 3.3% of her study cohort. Bleeding, in the present study, was mostly heavy in those patients who had non-viable pregnancies, whereas, those who had viable pregnancies had spotting.

Bhattu and Prajapati^[14] found that the majority 42 (38%) of first trimester bleeding patients presented at 8-10 weeks which was comparable to that reported by Bharadvaj *et al.*^[15] where 35% patient presented between 8-10 weeks. Hence the study shows agreement as per history and ultrasound findings. In contrast, Kamble *et al.*^[11] reported most frequent bleeding at <6 weeks. Almost two-thirds of the cases in his cohort occurred at <6 weeks of gestational age. Gollapalli and Gunda^[16] reported that at the time of bleeding, majority cases (60.5%) had more than 8 weeks of gestation and 39.5% had bleeding at less than 8 weeks of gestation. A study by Shivanagappa *et al.*^[17] noticed that majority cases had vaginal bleeding between 6-8 weeks (35%), followed by, 10-12 (33%) weeks and 8-10 weeks of gestation (32%).

In 68.1% of the participants, in the present study, could be continued beyond first trimester, of whom 11.6% had a favourable outcome, 56.5% had unfavourable outcome. This is comparable to the study done by Suganya and Subbarayan^[18] which reported that 16.7% of mothers with first trimester vaginal bleeding had a good outcome. This result suggests that women who are having first trimester abortion, if given proper antenatal care and by routine ultrasound and regular follow up and specific management, they can deliver a live term baby with minimal complications. Saraswat *et al.*^[19] performed a systematic review and demonstrated that first trimester bleeding has no effect on route of delivery. But some other studies have shown that possibility of caesarean section in women with bleeding is more than others. Lewis *et al.*^[20] reported that 28.86% mothers in their cohort underwent LSCS, similar to proportions reported by Davari-Tanha *et al.*^[21] (28%). In the present cohort, 29% neonates had birth weight >2500 g, followed by extremely LBW (ELBW) in 18.8%. Low birth weight (LBW) in 14.5% and very low birth weight (VLBW) infants in 5.8% of cases. Kamble *et al.*^[11] reported that 88.12% babies had birth weight >3 kg. In the study by Gollapalli and Gunda^[16] 56.89% cases had child with birth weight between 2.6-3 kg. Study by Patel *et al.*^[22] noticed that 44% newborn babies weighing 2.6-3 kg, 88.12% babies had birth weight more than 3.45 kg. The commonest neonatal complication seen in the study population was delivery of preterm infant (48.9%), followed by

normal weight infants (19.1%) and IUGR (17%). In our study 47 continued beyond 1st trimester out of which 3 underwent second trimester abortion out of remaining 44 delivered, out of 44 neonates born 34 infants required NICU admission (49.2%) and 10 did not require NICU. This is in contrast with studies done by Amirkhani *et al.*^[23] which showed NICU admission of only 16% infants.

Approximately one-third (31.9%) of the pregnancies were terminated, 30.4% had APGAR scores ≥ 7 , while 37.7% of the infants had APGAR score of <7 at the end of 5 min. Suganya and Subbarayan^[18] reported that 10% of women in the case (first trimester bleeding) group had low APGAR score when compared to 3.3% in the control group. Apgar score less than 7 has been reported with first trimester vaginal bleeding in many others studies. Bhatu *et al.*^[14] non-viable pregnancy outcome in their reporting cohort. Reddirani *et al.*^[24] reported 61% abortion and while Sofat *et al.*^[25] reported 70% abortions in their cohort of mothers with first trimester bleeding and a non-viable pregnancy^[25]. Kamble *et al.*^[11] showed that of all patients who aborted missed abortion (48.70%), subchorionic hematoma (7.70%), complete abortion (11.3%), incomplete abortion (28.20%) and IUFD (3.67%). In the present study, among viable fetus on USG, pre-term labour was seen 32.4%, normal delivery in 23.5%, pregnancy induced hypertension and post-partum hemorrhage in 11.8%, PROM in 8.8%, antepartum hemorrhage and oligohydramnios in 5.9%. Bhatu *et al.*^[14] reported that 20.7% of viable pregnancies on USG, had preterm delivery, 8.6% had IUGR. Bhatu *et al.*^[14] also reported anemia (31%), placenta previa (2.8%), placenta abruption (8.5%), PPROM (20%) and PIH (8.5%) in their study population. Hence, significant maternal morbidities are associated with patients who had bleeding per vaginum in their first trimester. Thus, bleeding per vaginum can prognosticate the complications in the pregnancy. Kamble *et al.*^[11] on the other hand, reported preterm labour in most patients (15.3%), PROM (6.75%), Antepartum haemorrhage (APH) (1.8%) and second trimester abortion (1.8%).

In the present study, unfavorable outcomes recorded were preterm infants (17.4%), premature rupture of membranes (13%), oligohydramnios (7.2%), post-partum hemorrhage (5.8%), second trimester abortion (4.3%) and APH like second trimester bleeding (2.9%). Yakıştıran *et al.*^[26] reported that incidence of preterm delivery, abortion, lower gestational fetal weight and preterm rupture of membrane was increased in threatened miscarriage group, when compared to another group with n first trimester bleeding. In their systematic review, Saraswat *et al.*^[19] reported that women with threatened miscarriage had a significantly higher incidence of antepartum

hemorrhage due to placenta praevia or antepartum hemorrhage of unknown origin compared with those without first-trimester bleeding. They were more likely to experience PPROM, preterm delivery and to have babies with intrauterine growth restriction. First-trimester bleeding was associated with significantly higher rates of perinatal mortality and low-birth weight babies. Maiti, evaluated the risk of adverse pregnancy outcomes in 120 women presenting with first trimester threatened miscarriage in a tertiary care center and found significant higher rates of placental abruption, pregnancy induced hypertension and fetal growth restriction.

The study does have its strength and limitations. The former includes a prospective study with modest sample size. Limitations include single centred study with non-comparative design limits generalizability of outcomes. Since it's a tertiary referral center an element of referral bias cannot be ruled out. Nevertheless the decent outcomes obtained act as a reference for future studies in India and abroad.

To summarize, pregnant women presenting with first-trimester vaginal bleeding are at high risk for loss of pregnancy and adverse outcomes in terms of preterm birth and need for NICU care. It is necessary to provide proper counseling regarding the possible outcome of pregnancy. A precise treatment and planning of future pregnancy is very essential in such women with pregnancy loss to prevent similar adverse outcomes.

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