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Indian Journal of Obstetrics and Gynecology Research

Journal homepage: [www.ijogr.org](http://www.ijogr.org)

## Original Research Article

## Does threatened miscarriage have an influence on maternal &amp; fetal outcomes during pregnancy? - Our experience in Kozhikode, North Kerala

Saikrishna Narayanan<sup>1\*</sup>, Ambika Prema Rajan<sup>1</sup>, Fathimathul Jusna Kalliyil<sup>1</sup>, Lakshmi Rajappan Nair<sup>1</sup>, Tajunnisa M Tajunnisa<sup>2</sup>, Heera Shenoy T<sup>1</sup><sup>1</sup>Dept. of Obstetrics and Gynaecology, Malabar Medical College Hospital and Research Center, Kozhikode, Kerala, India  
<sup>2</sup>Aster MIMS Hospital, Kozhikode, Kerala, India

## ARTICLE INFO

## Article history:

Received 02-02-2024

Accepted 06-05-2024

Available online 20-08-2024

## Keywords:

Threatened miscarriage

Adverse pregnancy outcomes

PPROM

Fetal growth restriction

Low birth weight

## ABSTRACT

**Background:** Bleeding in early pregnancy is a threat to developing embryo and constitute a significant source of anxiety to both parents, obstetrician. Adverse outcomes included miscarriage, placenta previa, abruption, preeclampsia, caesarean section, preterm labor, and preterm premature rupture of membranes, fetal growth restriction, and low birth weight.**Aim and Objectives:** The aim of this study was to find the association between threatened miscarriage and adverse pregnancy outcomes in both mother and fetus. Objective was to compare the pregnancy outcomes in normal patients (controls) and in those with threatened miscarriage (cases).**Materials and Methods:** A 1 year prospective study was conducted in Kozhikode; Kerala. The study included 140 antenatal patients who were grouped into 70 cases and 70 controls.**Results:** P-value is less than the significance level 0.05. It was found that caesarean section was significantly higher in case (66.2%) than control (42.9%). Pre-term delivery was also found to be higher in case (60.3%) compared to control (15.7%). PPROM was significantly higher in case (11.4%) compared to control (2.9%). Low birth weight was also higher in case (16.2%) than control (1.4%).**Conclusion:** There was significant association between threatened miscarriage and outcomes like Preterm Labor, preterm premature rupture of membranes, caesarean section, fetal growth restriction, and low birth weight. There was no significant association between threatened miscarriage and outcomes like miscarriage, placenta previa, placental abruption, preeclampsia.This is an Open Access (OA) journal, and articles are distributed under the terms of the [Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License](https://creativecommons.org/licenses/by-nc-sa/4.0/), which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.For reprints contact: [reprint@ipinnovative.com](mailto:reprint@ipinnovative.com)

## 1. Introduction

The word abortion gets its origin from the Latin word aboriri which means to miscarry. Miscarriage and abortion are used interchangeably. Miscarriage is defined as the termination of pregnancy before the period of fetal viability. National Center for health statistics, Centers for Disease control and prevention (CDC), and WHO define miscarriage as the termination of pregnancy with fetal weight less than 500g before 20 weeks of gestation. Miscarriage can be

either spontaneous / induced. Spontaneous miscarriage is the unintentional termination of pregnancy before 20 weeks. Spontaneous miscarriage can be divided into different types based on clinical and ultrasound findings. This includes threatened, inevitable, incomplete, complete, and missed miscarriage.

Threatened miscarriage is defined as presence of vaginal bleeding before 20 weeks of gestation<sup>1</sup> about 16-25% of pregnant women have vaginal bleeding in early pregnancy.<sup>1</sup> Threatened miscarriage is diagnosed in clinical practice with a history of vaginal spotting or bleeding and finding of closed cervix on vaginal examination. A

\* Corresponding author.

E-mail address: [heerarprabhu@gmail.com](mailto:heerarprabhu@gmail.com) (S. Narayanan).

definitive diagnosis of threatened miscarriage is made after performing ultrasound examination, by documenting the presence of fetal cardiac activity in an intrauterine pregnancy.

Threatened miscarriage is associated with increased risk of adverse outcomes including both maternal and fetal in case of continuing pregnancy. Maternal outcomes included miscarriage, placenta previa, abruption, preeclampsia and caesarean section. Fetal outcomes included preterm labor, preterm premature rupture of membranes, fetal growth restriction, low birth weight.

Bleeding in early pregnancy represents a threat to developing embryo and constitutes a significant source of anxiety to both the parents and the obstetrician. Education of the patient is significant in early pregnancy complications as this can be of significant distress to women and their partners and so proper information and support should be provided to them in a sensitive manner. Follow up care with an obstetrician must be in a coordinated manner. Clear instructions must be given to all patients with threatened miscarriage at the time of discharge. The pregnancy loss is often distressing for women and their partners, with adverse effects on their social and psychological well-being. It is relevant for both pregnant women and their obstetricians to know about the possible outcomes of pregnancy following first trimester bleeding to plan the antenatal care.

Knowledge of this increased risk may help indecision making regarding management, for example, timely administration of antibiotics and corticosteroids and to take decisions regarding mode and timing of delivery, which can definitely make an improvement in both maternal and fetal outcome.

## 2. Aim and Objectives

The aim of this study was to find the association between threatened miscarriage and adverse pregnancy outcomes in both mother and fetus. Objective was to compare the pregnancy outcomes in normal patients (controls) and in those with threatened miscarriage (cases).

## 3. Materials and Methods

### 3.1. Study population

This case control study was done in 140 antenatal patients, who were enrolled into cases and control of 70 each, below 20 weeks of gestation who attended the OPD/ IP in Department of Obstetrics and Gynecology of Malabar Institute of Medical Sciences Hospital and Research Centre, Kozhikode fulfilling the inclusion and the exclusion criteria.

### 3.2. Inclusion criteria

1. Singleton pregnancy presenting with vaginal bleeding or spotting.

2. Gestational age at or less than 20 weeks.
3. Intrauterine pregnancy with viability documented on USG.

### 3.3. Exclusion criteria

1. Medical diseases like Pregestational diabetes, Chronic Hypertension, Hypothyroidism.
2. History of recurrent miscarriage
3. Ectopic pregnancy, multiple pregnancy.
4. Uterine anomalies, presence of fibroids

### 3.4. Study duration

1 year (September 2019 - August 2020)

### 3.5. Study design

Case control study.

### 3.6. Sample size

$$N = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \cdot (p_1(1-p_1) + p_2(1-p_2))}{(p_1 - p_2)^2}$$

Where  $Z_{\alpha/2}$  is the critical value of the Normal distribution at  $\alpha/2$ .  $Z_{\beta}$  is the critical value of the Normal distribution at  $\beta$  and  $p_1$  and  $p_2$  are the expected sample proportions of the two groups. We had  $P_1 = 22.9\%$  and  $P_2 = 5.7\%$ . Taking alpha as 5% and power as 80%. The sample size obtained was 62. Considering a 10% lost to follow up, approximate sample size was 70 each.

After getting informed consent, the patient details as regard to age, MIMS number were recorded. A detailed obstetric history was taken regarding period of amenorrhea, amount of vaginal bleeding, association with pain. General physical examination and obstetrical examination was done.

### 3.7. Methods

70 cases who presented with threatened miscarriage at or below 20 weeks of gestation underwent ultrasound for documenting fetal viability. The diagnostic criteria for threatened miscarriage were based on documenting the fetal cardiac activity on ultrasound in those who presents with a history of vaginal bleeding in the presence of closed cervix.<sup>2</sup> Cases were matched for age to 70 controls who had attended OPD/IP during the same period. Controls were excluded if they had a history of bleeding in early pregnancy.

All ultrasound examinations were done using GE logic 200, in a frequency of 3.5 and 6.5 MHz for Trans abdominal and transvaginal scan respectively. On ultrasound, gestational age, fetal cardiac activity, presence of uterine anomalies and fibroids were noted. All patients in both groups were followed up till delivery to screen the pregnancy outcomes. Both maternal and fetal outcomes were assessed. Outcomes noted were Miscarriage, Placenta previa, Placental abruption, Preeclampsia, Preterm labor,

preterm premature rupture of membranes (PPROM), caesarean section, fetal growth restriction (FGR), low birth weight (LBW).

3.8. Statistical methods

Data was analyzed using SPSS 21.0 and graphs were depicted using Microsoft excel or open office Spreadsheet. Continuous variables were summarized as Mean ± Standard deviation or median with inter quartile range. Categorical variable had been summarized in terms of frequency with percentage and were tested using ChiSquare/ Fisher exact test. Independent t test was used for comparison of mean in two groups.

4. Results

Table 1: Distribution of maternal age

| Age (Years) | Control (N=70) | Case (N=70) | Total (N=140) | p-value |
|-------------|----------------|-------------|---------------|---------|
| 20–25       | 17(24.3%)      | 17(24.3%)   | 34(24.3%)     | 0.576   |
| 26–30       | 31(44.3%)      | 24(34.3%)   | 55(39.3%)     |         |
| 31–35       | 21 (30.0%)     | 27(38.6%)   | 48(34.3%)     |         |
| 36–40       | 1(1.4%)        | 2(2.9%)     | 3(2.1%)       |         |
| Mean±SD     | 28.3±4.22      | 29.5±4.05   | 28.9±4.16     |         |

The average age was 28.9 years with standard deviation 4.16. The minimum and maximum age was 20 and 40 years respectively.(Table 1)

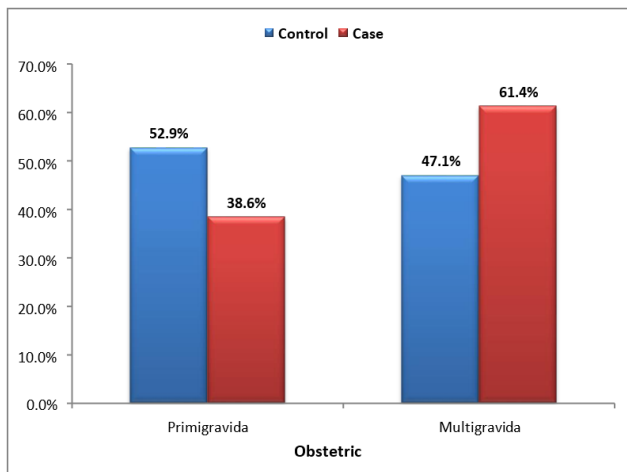


Figure 1: Distribution of obstetric score

Around 45 7% of the cases were Primigravida and 54 3% of the cases were Multigravida.(Figure 1)

The Table 2 reveals that the samples with gestational age 28-34 weeks and 34-37 weeks are significantly higher in case (17.6% & 41.2%) compared to control (1.4% &

Table 2: Comparison of gestational age at delivery

| Gestational Age (Weeks) | Control (N=70) | Case(N=68) | p-value |
|-------------------------|----------------|------------|---------|
| <28                     | 0(0.0%)        | 1(1.5%)    | 0.000   |
| 28–34                   | 1(1.4%)        | 12 (17.6%) |         |
| 34–37                   | 10 (14.3%)     | 28 (41.2%) |         |
| >37                     | 59 (84.3%)     | 27 (39.7%) |         |
| Mean±SD                 | 37.9± 1.21     | 35.4± 2.76 |         |

14.3%).

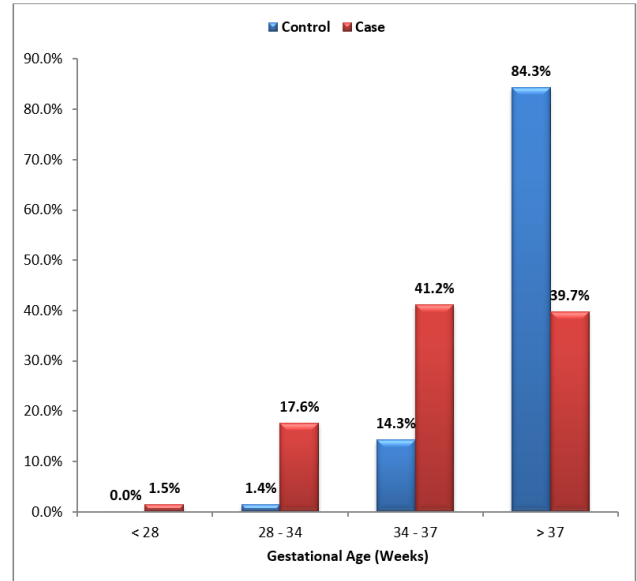


Figure 2: Comparison of gestational age at delivery

It is noted from the Figure 2 that the samples with gestational age more than 37 weeks is significantly higher in control (84.3%) compared to case (39.7%).

Table 3: Comparison of type of delivery between groups

| Type of Delivery  | Control (N=70) | Case(N=68) | p-value |
|-------------------|----------------|------------|---------|
| Vaginal Delivery  | 40 (57.1%)     | 23(33.8%)  | 0.000   |
| Caesarean Section | 30 (42.9%)     | 45(66.2%)  |         |

Here the p-value is less than the significance level 0.05. The Table 3 reveals that the caesarean section is significantly higher in case (66.2%) compared to control (42.9%).

Table 4: Comparison of miscarriage between groups

| Miscarriage | Control (N=70) | Case (N=70) | p-value |
|-------------|----------------|-------------|---------|
| No          | 70 (100.0%)    | 68 (97.1%)  | 0.094   |
| Yes         | 0(0.0%)        | 2(2.9%)     |         |

The Table 4 reveals that the miscarriage is almost same in control (0.0%) and case (2.9%).

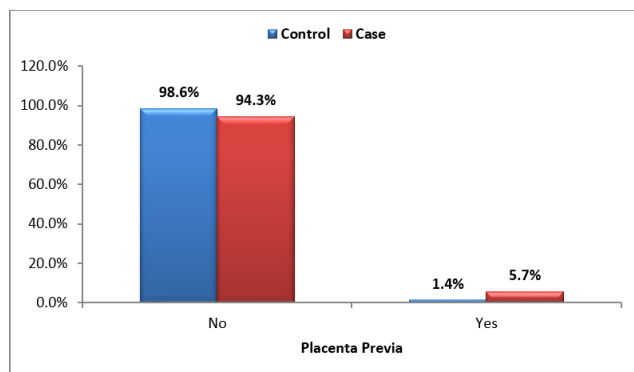


Figure 3: Comparison of placenta previa between groups

From the Figure 3 it is seen that placenta previa is same in cases and controls.

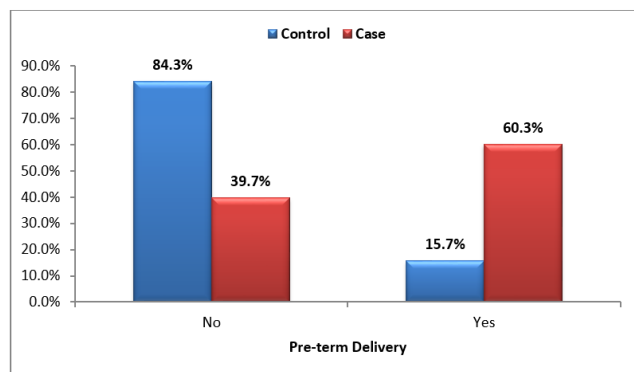


Figure 4: Comparison of pre-term delivery between groups

It is found from the Figure 4 that preterm delivery is higher in cases than controls.

Table 5: Comparison of abruption between groups

| Abruption | Control (N=70) | Case (N=70) | p-value |
|-----------|----------------|-------------|---------|
| No        | 70 (100.0%)    | 68 (97.1%)  | 0.094   |
| Yes       | 0(0.0%)        | 2(2.9%)     |         |

Here the p-value is greater than the significance level 0.05. The Table 5 reveals that the abruption is almost same in controls (0.0%) and cases (2.9%).

From the Figure 5 it is seen that preeclampsia was same in both cases and controls.

Table 6: Comparison of PPRM between groups

| PPROM | Control (N=70) | Case (N=70) | p-value |
|-------|----------------|-------------|---------|
| No    | 68 (97.1%)     | 62(88.6%)   | 0.042   |
| Yes   | 2(2.9%)        | 8(11.4%)    |         |

Here the p-value is less than the significance level 0.05; The Table 6 reveals that PPRM is significantly higher in case (11.4%) compared to control (2.9%).

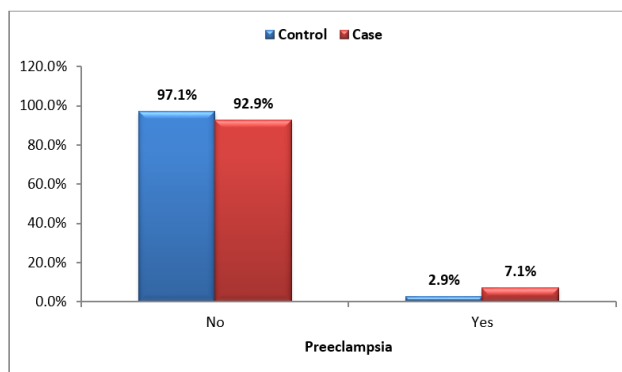


Figure 5: Comparison of preeclampsia between groups

Table 7: Comparison of IUGR between groups

| IUGR | Control (N=70) | Case (N=70) | p-value |
|------|----------------|-------------|---------|
| No   | 70 (100.0%)    | 60(85.7%)   | 0.000   |
| Yes  | 0(0.0%)        | 10(14.3%)   |         |

Here the p-value is less than the significance level 0.05; The Table 7 reveals that the IUGR is significantly higher in case (14.3%) compared to control (0.0%).

Table 8: Comparison of low birth weight between groups

| Low Birth Weight | Control (N=70) | Case (N=68) | p-value |
|------------------|----------------|-------------|---------|
| No               | 69 (98.6%)     | 57(83.8%)   | 0.001   |
| Yes              | 1(1.4%)        | 11(16.2%)   |         |

Here the p-value is less than the significance level 0.05; The Table 8 reveals that the low birth weight cases are significantly higher in case (16.2%) compared to control (1.4%).

### 5. Discussion

Miscarriage is defined as the termination of pregnancy either spontaneous/induced before the period of fetal viability. Most accepted definition by the World Health Organization (WHO) is that, Miscarriage is “the expulsion or extraction from its mother of an embryo or fetus weighing 500 gm or less before 20 weeks of gestation”.<sup>3</sup>

Threatened miscarriage is one of the commonest early pregnancy complications which accounts for the emotional burden on the pregnant women in one – fifth of cases. Most of the time, these patients are reassured and given empirical treatment.<sup>4</sup> Although many women with threatened miscarriage are treated with progesterone and bed rest, little evidence supports these policies. In the recent years many investigators have turned out to find the long -term impact of threatened miscarriage on pregnancy outcome, even though the exact etiology of this association is still debatable. Some studies have shown that if pregnancy continues, the suboptimal events will be more; like preterm

delivery, PPRM, Placental abruption, Preeclampsia, small for gestational age, cesarean deliveries. Some studies did not show any significant adverse effects by threatened miscarriage on the maternal-fetal outcome. In a study by Das et al.,<sup>5</sup> there was no report of any increase in the rate of poor pregnancy outcome like preterm delivery, SGA, and overall perinatal outcome in the women with threatened miscarriage.

Coming to maternal age, the minimum age being 20 and maximum age of 40 majorities of patients were Multigravida (54.3%) and remaining 45.7% of the cases were first time mothers. In our study most of the patients in case group delivered at gestational age of 28-34 weeks and 34-37 weeks 17.6% & 41.2% respectively. In the present study, the incidence of caesarean section is significantly higher in cases (66.2%) compared to control (42.9%). Incidence of vaginal delivery is higher in control group (57.1%) when compared to case (33.8%) Weiss et al<sup>6</sup> as well as Wijesiriwardana et al<sup>7</sup> & Kanmaz et al<sup>8</sup> had findings as in the present study. As gestational age at delivery is concerned, Batzofin et al<sup>9</sup> observed that preterm deliveries were significantly more as that in Weiss et al,<sup>6</sup> Saraswat et al.<sup>2</sup> Johns et al<sup>10</sup> supported this observation. Ahmed et al<sup>11</sup> as well as the present research had similar findings of placenta praevia. The incidence of hypertensive disorders of pregnancy is comparable in controls (2.9%) and cases (7.2%) as in Dadkhah et al<sup>12</sup> Preterm premature rupture of membranes is significantly higher in cases (11.4%) compared to controls (2.9%) as in Johns et al<sup>10</sup> Lykke et al.<sup>13</sup> Davari Tanha<sup>14</sup> further supported these findings. Fetal growth restriction is significantly higher in cases (14.3%), than controls as in the research conducted by Weiss et al and Saraswat et al<sup>2,6</sup> Babies of low -birth weight were significantly higher in cases (16.2%) compared to controls (1.4%) as in Batzofin et al<sup>9</sup> Ahmed et al<sup>12</sup> and that of Williams et al.<sup>15</sup>

## 6. Conclusion

Significant association was noted between threatened miscarriage and adverse pregnancy outcomes like Preterm labor, Preterm premature rupture of membranes, Caesarean section, fetal growth restriction and Low birth weight. There was no significant association between threatened miscarriage and outcomes like miscarriage, placenta praevia, placental abruption, preeclampsia.

## 7. Limitation

As this was a single center, hospital based study and it does not represent an entire population and as our sample size was relatively small, our results may have less statistical power, and it is difficult to draw a definite conclusion.

## 8. Recommendations

Threatened miscarriage should alert the clinician about the possible adverse pregnancy outcomes. A specific evidence based algorithm should be considered in the management of threatened miscarriage rather than empirical treatment with adequate counseling on prospective outcomes.

## 9. Author Contribution

Dr Saikrishna N prepared the protocol, collected data, assessed eligibility and methodological quality of studies and wrote the review. Dr Tajunnisa M conceived the idea, conducted searches, assessed eligibility and quality of studies. Dr Ambika and Dr Lakshmi Nair provided comments on the manuscript. Dr Fathimathul Jusna performed the statistical analysis and Dr Heera Shenoy T conceived the idea, provided comments on the manuscript and supervised the review.

## 10. Sources of Funding

None.

## 11. Conflict of Interest

None.

## 12. Ethical Consideration


The ethical approval for the research was provided by the following institutions, MIMS Kozhikode according to the principles of Helsinki Declaration.

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### Author biography

**Saikrishna Narayanan**, Assistant Professor  <https://orcid.org/0009-0003-7378-7270>

**Ambika Prema Rajan**, Assistant Professor

**Fathimathul Jusna Kalliyil**, Assistant Professor  <https://orcid.org/0009-0007-4020-2378>

**Lakshmi Rajappan Nair**, Assistant Professor

**Tajunnisa M Tajunnisa**, Senior Consultant

**Heera Shenoy T**, Professor  <https://orcid.org/0000-0001-6197-0236>

**Cite this article:** Narayanan S, Rajan AP, Kalliyil FJ, Nair LR, Tajunnisa TM, Shenoy T H. Does threatened miscarriage have an influence on maternal & fetal outcomes during pregnancy? - Our experience in Kozhikode, North Kerala. *Indian J Obstet Gynecol Res* 2024;11(3):345–350.