Comparison of active versus expectant management on fetomaternal outcome in patients with placenta previa

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ABSTRACT

Background: Placenta previa is one of the leading cause (31%) of obstetric hemorrhage. It accounts for significant maternal and perinatal morbidity and mortality. The objective of the present investigation was to compare the effect of active management versus expectant management on maternal and fetal outcome in patients with placenta previa.

Methods: This randomized prospective cohort study was conducted on 100 Patients of 32 weeks to 36 weeks of gestation with diagnosis of Placenta previa. Selected patients were randomly divided into Group A- Active management and Group B - Expectant management.

Results: In both the groups, majority of women were in the age group of 26-30 years and were multigravidas. The need for blood transfusion and the mode of delivery were similar in both the groups. Group A had higher incidence of PPH (22% vs 10%) and peripartum hysterectomy (18% vs 2%) when compared to group B. The maternal deaths were more in group A (4% vs 2%). Majority of the babies born to group A mothers had a low Apgar, birth weight below 2 kgs and greater NICU admission. The perinatal deaths were more in group A (16% vs 2%) and the difference was statistically significant.

Conclusions: The expectant management protocol was concluded to be a better mode of management protocol in patients with placenta praevia, who are either asymptomatic or with mild to moderate bleeding.

Keywords: Maternal outcome, Placenta previa, Postpartum hemorrhage, Peripartum hysterectomy, Prematurity, Perinatal outcome

INTRODUCTION

In the developing countries, obstetrical hemorrhage is an important cause for maternal mortality and morbidity. Placenta previa is one of the leading cause (31%) of obstetric hemorrhage.1 It also accounts for significant perinatal morbidity and mortality.2 Placenta previa is characterized by placental implantation into the lower segment of the uterine wall, covering whole (major) or part (minor) of the cervix.3 Placenta previa is graded into different types depending on how close is the lower margin of the placenta to the internal os and whether it is situated anterior or posterior wall of the uterus.4 The incidence of placenta previa is approximately 4-5 per 1000 deliveries.5,6 Ultrasound is the imaging modality of choice for localization of the placenta. Approximately 43% of cases were diagnosed by ultrasonography...
performed for other obstetrical reasons prior to the onset of vaginal bleeding.\(^7\)

 Mothers with placenta previa present with painless vaginal bleeding after fetal viability but before delivery. The bleeding is usually mild and recurrent. These patients along with those diagnosed prenatally are managed conservatively by expectant treatment. But sometimes bleeding can be massive and life threatening. Such cases are managed by emergency surgical interventions and immediate delivery. Active treatment is associated with severe maternal and perinatal morbidity and sometimes mortality. Whether diagnosed before or not, these patients have more intraoperative risks than who are managed electively. This problem is more pronounced in developing countries where few women attend antenatal care, shortage of blood for transfusion and delay of operative delivery due to logistic issues.\(^8\) Most neonatal morbidity and mortality associated with placenta previa are due to complications of prematurity.\(^9\)

Thus, this study was designed to compare the effect of active management versus expectant management on maternal and fetal outcome in patients with placenta previa.

**METHODS**

**Material**

- Patients with placenta previa fulfilling the inclusion and exclusion criteria.
- Patients willing for admission and consenting for the study.
- Sonography-Transabdominal (3-5Mhz) Doppler flow study.
- Emergency obstetric services for immediate intervention.
- Blood bank services

This study duration was 2014 to 2015. First 100 diagnosed cases of placental previa amongst all antenatal cases between 32 to 36 weeks attending outpatient Department or admitted in the Sri Lakshmi Narayana Institute of Medical sciences, Pondicherry during the study. The type of study conducted was randomized prospective cohort study.

**Inclusion criteria**

- Antenatal cases of gestational age of 32-36 weeks diagnosed as placenta previa
- Low risk category

**Exclusion criteria**

- Patients in high risk category
- Gestation < 32 and >36 weeks
- Local cervicovaginal cause of bleeding
- Trauma
- Systemic bleeding disorders
- Bleeding of undetermined origin
- Excessive show
- Marginal vein bleeding.

**High risk category**

1. Recurrent or continuous bleeding
2. Oligohydraminos
3. Premature rupture of membranes
4. Uterine hypertony
5. Non reactive NST
6. Major placenta previa.

**Low risk category**

1. Small subchorionic hemorrhage
2. Few bleeding episodes Premature rupture of membranes
3. Reactive NST
4. Minor placenta previa
5. Patient haemodynamically stable.

Patients of 32 weeks to 36 weeks of gestation with diagnosis of Placenta previa were included. Selected patients were randomly divided into groups A and B: Group A- Active management, Group B - Expectant management. All the patients are subjected to relevant investigation and started on antenatal steroids if necessary. Appropriate antibiotics substituted. Assessment by ultrasound -localization of placenta was done. Maternal need for blood transfusion were noted. The admission to delivery interval was recorded. Necessary intervention like caesarean sections, peripartum hysterectomy, management of DIC are instituted according to the standard protocol followed in our institution. Patients were evaluated after delivery for the occurrence of Postpartum hemorrhage (PPH), and maternal mortality were recorded. The weight of the baby at delivery and the Apgar score of the baby at 1st and 5th minute were recorded. Any fetal complication including admission to Neonatal intensive care unit (NICU) and perinatal mortality were noted.

**Group A:** Active management: Prompt delivery irrespective of gestational age.

**Group B:** Expectant management: Continuation of pregnancy for fetal maturity without maternal compromise.

In both the groups, depending on obstetrical implication, vaginal delivery or caesarean section is performed.

**Statistical analysis**

Data were analyzed using the SPSS version 11.0 (Statistical package for social sciences, Inc 2001; Chicago). Descriptive statistics (mean, standard deviation) were calculated for continuous variables.
Proportions and percentages were calculated for categorical variables. Chi-square (non-parametric test) was appropriately used to examine the statistical significance of the differences between categorical distributions. The p value less than 0.05 was considered statistically significant.

RESULTS

The distribution of patients between both the management groups were statistically similar with regard to maternal age (Table 1), parity (Table 2) and gestational age (Table 3). In both the groups, majority of women were in the age group of 26 - 30 years and were multigravida.

Table 1: Distribution of groups according to maternal age.

| Maternal age (yrs) | Group A | Group B | p-value |
|-------------------|---------|---------|---------|
| Below 20          | 04   | 09   | 0.11 NS |
| 21-25             | 19  | 38  |         |
| 26-30             | 25  | 20  |         |
| Above 30          | 08  | 02  |         |
| Total             | 50  | 50  |         |

Table 2: Distribution of cases according to parity.

| Parity            | Group A | Group B | p-value |
|-------------------|---------|---------|---------|
| Primigravida      | 17     | 12     | 0.27 NS |
| Multigravida      | 33     | 24     |         |
| Total             | 50     | 50     |         |

Table 3: Distribution of cases according to gestational age.

| Gestational age   | Group A | Group B | p-value |
|-------------------|---------|---------|---------|
| 32-34 weeks       | 18     | 15     | 0.52 NS |
| 34-36 weeks       | 36     | 35     |         |
| Total             | 50     | 50     |         |

Table 4: Comparison of blood transfusion requirement in the management groups.

| Need for transfusion | Group A | Group B | p-value |
|----------------------|---------|---------|---------|
| No transfusion       | 18     | 15     | 0.56 NS |
| Blood transfusion < 2 units | 12  | 15  |   |
| Blood transfusion ≥ 2 units | 8  | 7   |   |
| Total                | 50     | 50     |         |

The need for blood transfusion (Table 4) and the mode of delivery (Table 7) were similar in both the groups. Majority of patients in both the groups had LSCS as the mode of delivery. The patients in group B, the expectant management group had a mean prolongation of gestational period of about 15.49 days (Table 5). Comparing the maternal outcome in both the groups (Table 6), group A had higher incidence of PPH (22% VS 10%) and peripartum hysterectomy (18% VS 2%) when compared to group B and the difference was statistically significant. The maternal deaths were more in group A (4% VS 2%) but the difference was not statistically significant.

Table 5: Admission to delivery interval in expectant management group.

| Admission delivery interval | Group B | Mean±SD |
|-----------------------------|---------|---------|
| Below 7 days                | 9       | 18      |
| 7-14 days                   | 10      | 20      |
| Above 14 days               | 31      | 62      |
| Total                       | 50      | 100     |

Table 6: Comparison of maternal outcome between management groups.

| Maternal outcome            | Group A | Group B |
|-----------------------------|---------|---------|
| Postpartum hemorrhage       | 11      | 22      |
| Peripartum hysterectomy     | 9       | 18      |
| Maternal deaths             | 2       | 4       |
| No complication             | 27      | 54      |
| Total                       | 50      | 100     |

Table 7: Relationship between mode of delivery to protocol adopted.

| Mode of delivery | Group A | Group B | p-value |
|------------------|---------|---------|---------|
| Normal delivery  | 9       | 18      | 0.24 NS |
| Instrumental delivery | 9  | 6   |   |
| LSCS             | 32      | 48      |         |
| Total            | 50      | 50      |         |

Table 8: Relationship between 1 minute apgar and management plan.

| 1 min Apgar score | Group A | Group B | p-value |
|-------------------|---------|---------|---------|
| < 5/10            | 31      | 10      |         |
| ≥ 5/10            | 19      | 40      |         |
| Total             | 50      | 50      |         |

About 60% of the babies born to group A mothers had an Apgar of less than 5/10 in the 1st minute of life when compared to 20% of babies born to group B mothers (Table 8). Similarly, 58% of the babies born to group A mothers had an Apgar of less than 5/10 in the 5th minute
of life when compared to 18% of babies born to group B mothers (Table 9). Both the differences were statistically very significant (p<0.001). About 72% of babies delivered under group B had birth weight above 2 kgs whereas only 28% of babies delivered under group A had birth weight above 2 kgs (Table 10). The difference was statistically very significant (p<0.001). About 60% of the babies born to group A mothers had admission in NICU when compared to 22% of babies born to group B mothers (Table 11) and the difference was statistically very significant (p<0.001). The perinatal deaths were more in group A (16% VS 2%) and the difference was statistically significant.

Table 9: Relationship between 5 minute Apgar and management plan.

| 5 min Apgar score | Group A | Group B | p  |
|-------------------|---------|---------|----|
| < 5/10            | 29      | 58      | 9  |
| ≥ 5/10            | 21      | 42      | 4  |
| Total             | 50      | 100     | 50 |

Table 10: Distribution of relationship between birth weight and management protocol.

| Birth weight (kg)    | Group A | Group B | p   |
|----------------------|---------|---------|-----|
| Below 1.5            | 6       | 12      | 4   |
| 1.5 - 2              | 30      | 60      | 10  |
| Above 2              | 14      | 28      | 36  |
| Total                | 50      | 100     | 50  |

Table 11: Distribution of NICU admission in both the groups.

| NICU admission       | Group A | Group B | p   |
|----------------------|---------|---------|-----|
| NICU admitted        | 30      | 60      | 11  |
| No NICU admission    | 20      | 40      | 39  |
| Total                | 50      | 100     | 50  |

DISCUSSION

Placenta previa is defined as implantation of placenta in lower uterine segment, overlying or approaching internal cervical os. It is one of the main causes of vaginal bleeding in the third trimester complicating 0.3% to 0.6% of all pregnancies. There is higher incidence of low lying placenta diagnosed sonographically in the second trimester which ranges from 6% - 46%; however this rate reduces to about 0.5% at delivery. Although the etiology of this condition remains unclear, several risk factors associated with this condition include advanced maternal age, multiple gestations, multiparity, tobacco use, a male fetus, previous history of placenta previa, previous uterine scar following instrumentations, myomectomy and previous caesarian delivery. Recurrent rate is 4 to 8% of subsequent pregnancies. Placenta previa increases the risk of maternal and fetal complications. The adverse maternal outcome like postpartum hemorrhage, cesarean hysterectomy, increased need for blood transfusion, bladder injuries are dreaded complications. On other hand, preterm birth, low birth weight, low APGAR score, respiratory distress syndrome 21 and need to NICU admission are important neonatal problems. Perinatal mortality in pregnancies complicated by placenta previa is approximately 4-8%. Ultrasound is the imaging modality of choice for localization of the placenta. Approximately 43% of cases were diagnosed by ultrasonography performed for other obstetrical reasons prior to the onset of vaginal bleeding. Compared to transabdominal ultrasound, Vaginal ultrasound is the most accurate method for localizing and diagnosing placenta previa, as it can provide a better resolution in the lower margin of the placenta. While marginal placenta previa could be delivered vaginally, caesarian section is reserved for some partial and total placenta previa including any type with life threatening bleeding.

The patients with placenta previa usually present with two clinical forms. The first clinical form is massive life-threatening vaginal bleeding for which patients with placenta previa most often require emergency surgical interventions and immediate delivery. The major goal is to achieve hemodynamic stability. In the second clinical form, patients with placenta previa are diagnosed prenatally or with a second trimester vaginal bleeding for which conservative management is successful. The major goal in this expectant line of management is to determine the progress of praevia with increasing gestational age and reduce the risk of re-bleeding and preterm birth. Whether diagnosed before or not, the patients managed on active treatment have many more intraoperative risks than patients with placenta previa who are delivered electively. Most neonatal morbidity and mortality associated with placenta previa are due to complications of prematurity. At the same time, most women who initially present with symptomatic placenta previa respond to supportive therapy and do not require immediate delivery. In observational series, 50 percent of women with a symptomatic placenta previa (any amount of bleeding) were not delivered for at least four weeks. Even a large bleed does not preclude conservative management. In one large series, 50 percent of women whose initial hemorrhagic episode exceeded 500 mL were successfully managed with aggressive use of antepartum transfusions and had a mean prolongation of pregnancy of 17 days.

An attempt has been made to understand the relationship between the management protocols of active versus expectant treatment for placenta previa to its association with the feto-maternal outcome.
In present study, both the groups were standardized for age (Table 1), parity (Table 2) and gestational age (Table 3). Many studies have demonstrated that increasing maternal age is an important risk factor for placenta previa.29 In present study, 11% of the patients were in the age group of less than 20 years and the rest (89%) were above the age of 20 years. In both the groups, majority of women were in the age group of 26-30 years. Though the incidence increases after the age of 30 yrs, this age range in present study is attributed to early marriages, which is more prevalent in our societies.

Again multiple studies had demonstrated that increasing parity is an important risk factor for placenta previa.16,30 Multigravida ≥5 pose a fivefold increase in risk of placenta previa.31 The increased risk of placenta previa among multigravidas women may be explained by degenerative change to the uterine vasculature, leading to under perfusion of the placenta, compensatory enlargement, and increased likelihood of implantation on the lower segment.32 In present study, 66% of group A mothers and 76% of group B mothers were multigravidas (Table 2). Accordingly, the mean percentage of multigravidas presenting with placenta previa was 71%, which is in accordance to the above studies. So being a problem of multiparity, reduction in family size and the issues of contraception are highly applicable if the incidence and associated morbidity and mortality are to be reduced.

**Antepartum morbidity**

Women with placenta previa had threefold higher odds for blood transfusion.33,34 In the present study, 24% of group A patients and 30% of group B patients required blood transfusion of less than 2 units. And 16% of group A and 14% of group B patients required transfusion of ≥2 units. The difference was not statistically significant because of the blood requirement in expectant group in the waiting period with on and off minimal hemorrhages. A delay in the correction of hypovolemia can be fatal in case of hemorrhage. But the blood transfusions do expose the patient to the risk of transfusion reactions and infections.

**Admission delivery interval**

According to a 2003 Cochrane review, expectant management with tocolysis was associated with prolongation of pregnancy (17.7days, p<0.05) and showed no increased risk of bleeding.35 Even a large bleed does not preclude conservative management. In one large series, 50 percent of women whose initial hemorrhagic episode exceeded 500 mL, were successfully managed with aggressive use of antepartum transfusions and had a mean prolongation of pregnancy of 17 days.9 In present study, 20% of the patients in group B had their gestational period prolonged to 7-14 days and 62% had their gestational period prolonged to more than 14 days. Hence the patients who underwent expectant management had a mean prolongation of gestational period of about 15.49 days (Table 5) which was well in correlation with other studies. This prolongation was due to the administration of tocolytics.

**Mode of delivery**

In present study, there was no statistically significant difference with regard to the mode of delivery. In group A, 64% of patients underwent caesarean section and it was 56% in group B. Love et al had reported 60% caesarean section rates in patients with mild placenta previa managed conservatively.36 Women with placenta previa had tenfold higher odds of Caesarean delivery.37 This can be explained by the fact that the placenta in the lower segment obstructs engagement of the head especially for major previa and may also cause the transverse lie of the fetus. That necessitates caesarean section.

**Intrapartum morbidity**

In population based retrospective cohort study in Nova Scotia, Canada, they had identified maternal complications like postpartum bleeding (RR-1.86), hysterectomy (RR 33.26), blood transfusion (RR-10.05), and septicemia (RR-5.55) in patients with placenta previa.38 Sheiner et al had found that pregnancies complicated by placenta previa had significantly higher rate of postpartum hemorrhage (OR: 3.8, 95%CI: 1.2-10.5), malpresentations (OR: 7.6, 95% CI: 5.7-10.1), abruptio placenta (OR: 13.1, 95% CI: 8.2-20.7).39 Anzaku et al had demonstrated complications like postpartum anemia (6.7%), caesarean hysterectomy (3.0%) and two maternal deaths (1.48%).40

In present study, the incidence of PPH and associated peripartum hysterectomy were significantly higher in group A and was statistically significant. Though the maternal deaths were more in group A compared to group B, the difference was not statistically significant.

Thus, the incidence of peripartum morbidity rates were lower in the expectant group because of elective induction and higher availability of resources for management of blood loss, manpower and theatre availability in elective situation.

**Fetal Outcome**

Many studies had demonstrated that infants born to women with placenta previa had increased odds of low birth weight, Apgar scores of <7, admission to neonatal intensive care unit, stillbirth, fetal malpresentation, and early neonatal deaths.34,35,40 Sheiner et al had showed that congenital malformations and perinatal mortality was 2.6 times more common among cases with placenta previa as compare to those without it. Increased perinatal mortality as well as neonatal death has been noted in other studies also.41
**Apgar score**

In present study, 62% of the babies in group A had Apgar of less than 5/10 at 1st minute of life whereas in group B, only 20% of the babies had an low Apgar score. Thus, the babies who were delivered by active management had 3 times increased chances of having low Apgar score at 1st minute when compared to babies delivered by expectant management. The difference was statistically very significant. Similarly, 58% of the babies in group A had Apgar of less than 5/10 at 5th minute of life whereas in group B, only 18% of the babies had a low Apgar score. Thus, the babies who were delivered by active management had 3 times increased chances of having low Apgar score at 5th minute when compared to babies delivered by expectant management. The difference was statistically very significant. The mean Apgar at 1st minute was 5.2 and 6.9 for group A and B respectively. And the mean Apgar at 5th minute was 7.1 and 8.1 respectively. The difference was statistically very significant. The higher Apgar values in the expectant group was due to the administration of steroids and increased gestational age.

**Birth weight**

In the present study, 72% of babies delivered in the expectant group had birth weight above 2 kgs whereas only 28% of babies delivered in active group was above 2 kgs. The mean birth weight in expectant group was 2.2 kgs whereas in active group it was 1.6 kgs only. Both the differences were statistically significant. The increased birth weight in the expectant group was due to the prolongation of the gestational age.

**NICU Admission and Perinatal deaths**

In the present study, 60% of the babies delivered in the active group had been admitted in NICU whereas only 22% of babies delivered in expectant group had NICU admission. This difference was statistically significant. The babies in the actively managed group had 3 times increased risk of admission to NICU than those of expectant management group. The reason for increased NICU admission in actively managed group was because of prematurity. There were 16% perinatal deaths in actively managed group compared to only 2% perinatal deaths in expectantly managed group. The factors like the aggressive use of antepartum transfusions in the face of moderate bleeding, use of tocolytic agents for inhibition of premature labour in the presence of vaginal bleeding, administration of steroids for lung maturity, increased gestational age and elective termination of pregnancy could have resulted in lower perinatal death rate with expectant management group.

**CONCLUSION**

The parity has an influence on placenta previa. Hence family Welfare services can help to reduce the family size and thereby the complications. The expectant management does not alleviate the need for blood transfusion or affect the mode of delivery significantly. The maternal and fetal morbidity and mortality were significantly much lower in the expectantly managed group than the actively managed group. Therefore, the expectant management protocol was concluded to be a better mode of management protocol in patients with placenta previa, who are either asymptomatic or with mild to moderate bleeding. But larger studies are warranted for assessing its efficiency.

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