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Original Research Article

ETIOLOGICAL EVALUATION OF CASES OF PRETERM LABOUR AND METHODS OF PREVENTION – A PROSPECTIVE STUDY

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ABSTRACT

Background: Preterm labour is defined as regular contraction of uterus resulting in changes in cervix that starts before 37 completed weeks of pregnancy. Changes include effacement and dilatation of cervix. First promulgated in 1976, WHO and the International Federation of Gynaecology and Obstetrics (FIGO) preterm infants were those delivered before 37 completed weeks, that is $\leq 36^{6}/_{7}$ weeks. The aim & objective is to identify the different etiological factors associated with preterm labour, assess the various preventive methods applied, and evaluate their effectiveness in relation to the overall maternal and perinatal outcomes.

Materials and Methods: A prospective analytical study was conducted in the Department of Obstetrics and Gynaecology, Calcutta National Medical College, Kolkata, West Bengal, India, over one year from July 2017 to June 2018. The study included 200 pregnant women with spontaneous preterm labour.

Results: Among 200 cases, PPROM was the commonest risk factor (17%), followed by PIH (10%) and maternal age >35 years (8%). Nifedipine, micronised progesterone and OHPC prolonged gestation, but without statistical significance. Most newborns weighed 1.5–2.5 kg (61.5%), while SNCU admission and low birth weight remained substantial.

Conclusion: We concluded that preterm labour is multifactorial, with PPROM as the commonest risk factor. OHPC showed the greatest numerical pregnancy prolongation, followed by nifedipine and micronised progesterone, though differences were not statistically significant. Low birth weight and SNCU admissions highlighted neonatal morbidity, emphasizing early risk identification, surveillance, and individualized management.

Keywords: Preterm labour, PPROM, Risk factors, Tocolysis , Preterm birth prevention.

INTRODUCTION

Preterm labour is defined as regular contraction of uterus resulting in changes in cervix that starts before 37 completed weeks of pregnancy. Changes include effacement and dilatation of cervix. First promulgated in 1976, WHO and the International Federation of Gynaecology and Obstetrics (FIGO) preterm infants were those delivered before 37 completed weeks, that is $\leq 36^{6}/_{7}$ weeks. This definition is in use for almost 40 years and is based on statistical analysis of gestational age distribution at birth. Beginning in 2005, in recognition that infants born between $34^{0}/_{7}$ weeks and $36^{6}/_{7}$ weeks experience morbidities and mortality characteristics of premature infants. Preterm births were subdivided as—i) 28 to $33^{6}/_{7}$ weeks are labelled early preterm"; ii) occurring between 34 and 36 completed weeks—late preterm. Preterm labour, defined as the onset of labour resulting in

birth before 37 completed weeks of gestation, remains one of the most important causes of perinatal morbidity and mortality worldwide. Approximately 13.4 million babies were born preterm globally in 2020, accounting for nearly one in ten live births, and complications related to prematurity remain a leading cause of mortality among children under five years of age.[1] Preterm birth is a heterogeneous condition resulting from multiple interacting maternal, fetal, placental and environmental factors. Important associated factors include PPROM, multiple pregnancy, maternal infections, hypertensive disorders, anaemia, extremes of maternal age and previous history of preterm birth.[1,2]

Despite advances in antenatal care, a substantial proportion of preterm births remain difficult to predict or prevent.Prevention and appropriate management of preterm labour require early identification of high-risk pregnancies, adequate antenatal surveillance and timely management of modifiable risk factors. Interventions such as progesterone therapy, cervical cerclage and appropriate management of infections may reduce the risk of spontaneous preterm birth in selected high-risk women.[3]

When preterm labour occurs, tocolytic therapy, particularly nifedipine in appropriately selected women, may provide a short period of pregnancy prolongation to facilitate antenatal corticosteroid administration and transfer to a facility with appropriate neonatal care.[4]

Management of PPROM is also an important component of reducing adverse maternal and neonatal outcomes.[5]

Therefore, systematic evaluation of the etiological factors and effectiveness of preventive and therapeutic measures is essential.

MATERIALS AND METHODS

Type of Study: Prospective analytical study.

Place of Study: Department of Obstetrics and Gynaecology, Calcutta National Medical College, Kolkata, West Bengal, India.

Study Duration: One year, from July 2017 to June 2018.

Sample Size: 200 pregnant women/cases of spontaneous preterm labour.

Inclusion Criteria:

1. All cases of spontaneous preterm labour.
2. Both primigravidae and multigravidae.
3. Pregnant women without gross medical disorders.
4. Patients fulfilling the study criteria and providing informed written consent.

Exclusion Criteria:

1. Cases with antepartum haemorrhage.
2. Cases with severe preeclampsia or eclampsia.
3. Cases with severe medical disorders, such as gross cardiac disease.
4. Cases requiring urgent and stringent management for maternal or fetal indications that could interfere with the study assessment.

Study Variables:

A. Maternal Variables

- Age of the mother
- Gravidity and parity
- Gestational age at admission
- Antenatal care status
- Relevant obstetric history
- Associated risk factors for preterm labour
- Maternal medical/obstetric complications

B. Risk Factor Variables

- Previous history of preterm delivery
- Obstetric risk factors
- Maternal medical conditions
- Other relevant risk factors associated with spontaneous preterm labour

C. Management Variables

- Nifedipine administration
- Magnesium sulphate administration
- Hydroxyprogesterone caproate administration
- Micronised progesterone administration
- Other applicable preventive/therapeutic measures
- Ultrasonographic assessment

D. Maternal Outcome Variables

- Gestational age at delivery
- Mode of delivery
- Duration of pregnancy prolongation, where applicable
- Maternal complications
- Outcome of management

E. Neonatal Outcome Variables

- Birth weight
- Gestational age at birth
- NICU admission
- Neonatal complications
- Overall neonatal outcome

Study Technique: The study evaluated the incidence of various risk factors associated with spontaneous preterm labour. Appropriate preventive and therapeutic measures were applied wherever indicated, and the outcome of management was assessed in terms of gestational age at delivery, birth weight, NICU admission and neonatal complications.

Statistical Analysis

Data were entered into Excel and subsequently analyzed using SPSS and GraphPad Prism. Continuous variables were summarized as means with standard deviations, while categorical variables were presented as counts and percentages. Comparisons between independent groups were performed using two-sample t-tests, and paired t-tests were applied for correlated (paired) data. Categorical data were compared using chi-square tests, with Fisher's exact test applied when expected cell counts were small. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

Table 1: Distribution of various risk factors among study population

S. No	Risk Factors	Number	Percentage %
1	PPROM	34	17%
2	PIH	20	10%
3	TWIN	11	5.50%
4	Maternal Age<20	10	5%
5	Maternal Age>35	16	8%
6	Anaemia	13	6.50%
7	UTI	13	6.50%
8	Oligohydramnios	11	5.50%
9	Malpresentation	8	4%
10	Vaginal Infections	2	1%
11	Fever	4	2%
12	Congenital Anomaly Of Fetus	2	1%
13	Previous History Of Abortions	11	5.50%
14	Previous History Of Preterm Delivery	11	5.50%

Table 2: Average lengthening of gestational period & neonatal birth weight with nifedepene

Mean Gestational Age at Admission (wks) (n=30)	Mean Gestational Age at Delivery (wks) After Nifedepene (n=30)	P Value	95% Confidence Level	Mean Birth Weight at Delivery (kg)	Total No. of SNCU Admission	>2.5 kg	1.5-2.5 kg	<1.5 kg
33.33	34.66	0.196	.22 to 2.4	2.16	7	9	18	3

Table 3: Average lengthening of gestational period & neonatal birth weight with micronised progesterone

Mean Gestational Age at Admission (wks)	Mean Gestational Age at Delivery (wks)	P Value	95% Confidence Interval	Mean Birth Weight at Delivery (kg)	Total No. of SNCU Admission	> 2.5	1.5 - 2.5	< 1.5
34	34.62	0.2102	-0.3594 to 1.5994	2.05	9	6	20	4

Table 4: Average lengthening of gestational period & neonatal birth weight with injection hydroxyprogesterone caproate use

Mean Gestational Age at Admission (wks)	Mean Gestational Age at Delivery (wks)	P Value	95% C.I. Level	Mean Birth Weight (kg)	Total SNCU Admission	>2.5	1.5-2.5	<1.5
33.49	34.94	0.3264	0.4600 to 1.3600	1.98	10	5	19	6

Table 5: Distribution of sncu admissions with respect to various management done

Management Applied	Number of Sncu Admissions (N=64)	Percentage % of Sncu Admission
Nifedipene (n=30)	7	23.33%
OMP (n=30)	9	30%
MgSO□ (n=30)	3	10%
OHPC (n=30)	10	33.33%
Cervical Cerclage (n=10)	7	70%
No Specific Management Done (n=70)	28	40%

Table 6: Distribution of birth weight of the newborns with respect to management applied

Birth Weight (Kgs)	Nifedipene	OMP	MgsO□	OHPC	Cervical Cerclage	No Specific Management Done	Total
>2.5	9	6	13	5	1	5	39
1.5–2.5	18	20	16	19	2	48	123
<1.5	3	4	1	6	7	17	38
Total	30	30	30	30	10	70	200

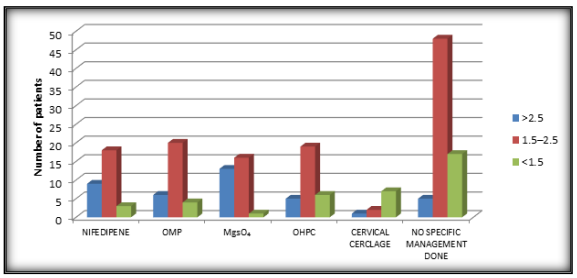


Figure 1: Distribution of Birth Weight of the New-borns with Respect to management applied

Among the 200 study participants, PPROM was the most common risk factor for preterm labour (17.0%), followed by PIH (10.0%), maternal age >35 years (8.0%), anaemia and UTI (6.5% each). Twin pregnancy, oligohydramnios, previous history of abortions and previous history of preterm delivery were each observed in 5.5% of cases. Maternal age <20 years was present in 5.0%, malpresentation in 4.0%, fever in 2.0%, and vaginal infection and fetal congenital anomaly in 1.0% each. Among women receiving nifedipine, the mean

gestational age increased from 33.33 to 34.66 weeks, while in the micronised progesterone group it increased from 34.00 to 34.62 weeks. With OHPC, the mean gestational age increased from 33.49 to 34.94 weeks. However, the observed differences were not statistically significant for nifedipine (p=0.196), micronised progesterone (p=0.2102), or OHPC (p=0.3264). Regarding neonatal outcomes, the mean birth weight was 2.16 kg in the nifedipine group, 2.05 kg in the micronised progesterone group and 1.98 kg in the OHPC group. SNCU admission occurred in 7 (23.33%) nifedipine, 9 (30.0%) OMP, 3 (10.0%) $MgSO_4$ and 10 (33.33%) OHPC cases, while 7 (70.0%) cases undergoing cervical cerclage and 28 (40.0%) receiving no specific management required SNCU admission. Overall, 123 (61.5%) newborns weighed 1.5–2.5 kg, 39 (19.5%) weighed >2.5 kg and 38 (19.0%) weighed <1.5 kg. The proportion of low birth weight <1.5 kg was highest in the cervical cerclage group (70.0%), followed by no specific management (24.3%) and OHPC (20.0%).

DISCUSSION

The present prospective analytical study evaluated the etiological factors associated with preterm labour and the outcomes following different preventive and therapeutic interventions among 200 women. Among the identified risk factors, PPROM was the most common (17.0%), followed by PIH (10.0%), maternal age >35 years (8.0%), anaemia (6.5%) and UTI (6.5%). Twin pregnancy, oligohydramnios, previous history of abortion and previous preterm delivery were each observed in 5.5% of cases. The predominance of PPROM in the present study is clinically relevant, as disruption of the fetal membranes is an important pathway leading to spontaneous preterm birth. The observed association of preterm labour with hypertensive disorders, maternal infections, extremes of maternal age and previous adverse obstetric history further supports the multifactorial aetiology of preterm birth, involving maternal, fetal, placental and infectious factors. Current recommendations for PPROM emphasize timely diagnosis, appropriate maternal and fetal surveillance and individualized management to reduce maternal and neonatal morbidity.[6] With respect to preventive and therapeutic management, women treated with nifedipine demonstrated an increase in mean gestational age from 33.33 weeks at admission to 34.66 weeks at delivery, corresponding to an observed prolongation of approximately 1.33 weeks. However, this difference was not statistically significant (p=0.196). Nifedipine is widely used as a calcium-channel blocker for tocolysis because of its ability to reduce myometrial contractility. The principal clinical objective of tocolysis is generally to obtain a limited period of pregnancy prolongation sufficient to facilitate administration of antenatal corticosteroids and, where necessary, maternal transfer to a facility with appropriate neonatal care rather than to prevent preterm birth permanently. The WHO recommendations support the use of nifedipine as a tocolytic agent in appropriately selected women with imminent preterm birth.[7] Thus, although the present study demonstrated a numerical prolongation of gestation, the absence of statistical significance indicates that the observed difference cannot be conclusively attributed to nifedipine alone. In the micronised progesterone group, the mean gestational age increased from 34.00 to 34.62 weeks, with an observed prolongation of approximately 0.62 weeks; however, the difference was not statistically significant (p=0.2102). Progesterone has an established biological role in maintaining uterine quiescence and cervical integrity, and its use has been investigated extensively for the prevention of spontaneous preterm birth. Evidence suggests that the benefit of progesterone is most apparent in selected high-risk populations, particularly women with a short cervix and/or a previous spontaneous preterm birth, rather than in an unselected population.[8,9] The relatively small prolongation observed in the present study may therefore reflect differences in patient characteristics, gestational age at initiation, indication for therapy, route and formulation of progesterone, and the fact that treatment in this study was evaluated in women who had already developed preterm labour. Treatment with hydroxyprogesterone capote (OHPC) resulted in an increase in mean gestational age from 33.49 to 34.94 weeks, representing an observed prolongation of approximately 1.45 weeks. Nevertheless, the difference was not statistically significant (p=0.3264). These findings are important in view of the continuing debate regarding the effectiveness of OHPC in preventing spontaneous preterm birth. More recent evidence has questioned the efficacy of OHPC, particularly for routine prevention of recurrent spontaneous preterm birth, and has led to increasing emphasis on individualized risk assessment and alternative evidence-based strategies. Therefore, the numerical prolongation observed with OHPC in the present study should be interpreted cautiously and should not be regarded as evidence of a statistically proven treatment effect. The neonatal findings further demonstrated the morbidity associated with preterm delivery. The mean birth weight was 2.16 kg in the nifedipine group, 2.05 kg in the micronised progesterone group and 1.98 kg in the OHPC group. Overall, 123 (61.5%) neonates had a birth weight of 1.5–2.5 kg, 39 (19.5%) weighed >2.5 kg and 38 (19.0%) weighed <1.5 kg. SNCU admission was required in 23.33% of neonates in the nifedipine group, 30.0% in the OMP group, 10.0% in the $MgSO_4$ group and 33.33% in the OHPC group. The relatively high SNCU admission rate among the cervical cerclage group (70.0%) and the no-specific-management group (40.0%) should be interpreted in the context

of their underlying obstetric risk and gestational age, as the present study was observational and treatment allocation was not randomized. Overall, the findings indicate that early identification of modifiable risk factors, appropriate antenatal surveillance and individualized management remain central to reducing the burden of preterm birth and its associated neonatal morbidity. The present study also suggests that although several interventions were associated with numerical prolongation of pregnancy, the lack of statistically significant differences warrants cautious interpretation and highlights the need for larger controlled studies to establish comparative effectiveness.

CONCLUSION

We concluded that preterm labour has a multifactorial aetiology, with PPROM being the most common risk factor, followed by PIH, advanced maternal age, anaemia and UTI. Nifedipine, micronised progesterone and OHPC were associated with numerical prolongation of gestational age; however, the observed differences were not statistically significant. Among these interventions, OHPC demonstrated the greatest mean prolongation of pregnancy, followed by nifedipine and micronised progesterone. A considerable proportion of neonates had low birth weight and required SNCU admission, highlighting the neonatal morbidity associated with preterm birth. Early identification of maternal and obstetric risk factors, appropriate antenatal surveillance, timely management of PPROM and associated complications, and individualized preventive and therapeutic interventions are essential for improving maternal and neonatal outcomes. Further large-scale prospective studies are warranted to determine the effectiveness of different preventive strategies in reducing preterm birth and its associated complications.

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