Original Research Article

Role of antenatal steroids in respiratory distress in late preterm

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Abstract

Background & Objectives: The current study was conducted to evaluate the utility of using steroids in mothers delivering between 34 to 36 weeks of gestational age (late preterm births) and neonatal outcomes such as need for resuscitation, NICU admission, APGAR scores, need for interventions such as oxygen supplementation, CPAP and mechanical ventilation. In addition, neonatal morbidity was also evaluated. **Methodology:** The study was double group, randomized study with interventional group (study group) and the comparator (control group) comprising of 100 patients each. The patients were randomly assigned to either of the group, however in case the delivery was inevitable before giving steroid injection the patients were invariably assigned to the control group. The steroid injections comprised of either dexamethasone 4 doses or betamethasone with a maximum of 2 doses given in the study group. Due consent was obtained from the patients satisfying the inclusion criteria of age above 18 years. **Results:** The mean gestational age in the interventional group was 34.58 weeks (SD:0.77) compared to 34.39 weeks (0.61) in the control group with a P value of 0.055 signifying a non-significant difference. The mean APGAR score at 1 minute was 5.35 in study group (SD:1.1) compared to 5.01 in control group (SD:1.23). 26 neonates in study group required resuscitative measures compared to 40 in the control group. 11 subjects each in study group developed transient tachypnoea of new born (TTNB) and Hyaline membrane disease whereas in control group there were 12 neonates with TTNB and 32 with Hyaline membrane disease. The difference was significant with a significantly higher incidence of hyaline membrane disease in control with P value of 0.0422. 5 males each and 6 females each had TTNB in study and control group respectively whereas 7 and 19 males had HMD, and 4 and 14 females had HMD in study and control group respectively. The difference was non- significant with P value of 1 for TTNB and significant with P value of 0.003 for HMD respectively, showing an increased incidence for HMD in male gender in control group. 15 neonates in study group required NICU admission compared to 27 in the control group. 7 neonates in study group required mechanical ventilation compared to 17 in the control group. 12 neonates in study group required oxygen supplementation compared to 23 in the control group. 22 neonates in study group required some or other intervention compared to 44 in the control group. 4 neonates in study group died compared to 12 in the control group. **Conclusion:** Steroids injections of either betamethasone or dexamethasone given to mothers expecting a preterm delivery between 34 to 36 weeks may have a beneficial effect on neonatal outcomes especially the respiratory parameters. We suggest use of antenatal steroids in prior to expected preterm births based on finding of our study.

Keywords: Steroids; PICU; Apgar score; Neonatal Outcome; Preterm birth; Betamethsone; Dexamethasone.

Introduction

The length of human pregnancy is variable. A normal pregnancy lasts between 38 and 42 weeks (260-294 days). This is referred to as a term pregnancy. Pregnancies that extend up to and beyond 42 weeks (294 days) are termed as post term pregnancies and those that end before 37 completed weeks are termed as preterm pregnancies.

Forty-five years ago, **Liggins and Howie** demonstrated that antenatal corticosteroid (ACS) use could significantly decrease respiratory distress syndrome (RDS) in live born infants less than 32 weeks gestation. Corticosteroids given to women at risk of preterm birth before 34 weeks reduce neonatal deaths, respiratory distress syndrome, intraventricular hemorrhage and necrotizing enterocolitis. However, the use of antenatal steroids after 34 weeks gestation is controversial.

Need for study

Late preterm are infants born between gestational age of 34 weeks and 0/7 days through 36 weeks and 6/7days (239th – 259th day). Incidence of preterm in India is 21%. Late preterm show increased incidence of Respiratory disorders than full term (29% v/s 4%) apnoea (6% v/s 0.1%), need for mechanical ventilation (3.45 v/s 0.9%). The most common respiratory disorders in late preterm are Transient tachypnea of newborn, Respiratory distress syndrome, Pneumonia, Pulmonary hypertension.

Late preterm are more prone develop RDS due to lack of clearance of lung fluid, relative deficiency of surfactant, lack of labour and related hormonal changes in cesarean section. Various investigations have suggested that antenatal treatment with antenatal corticosteroids could accelerate lung maturity in late preterm infants. This study is being done to assess the usefulness of antenatal steroids in preventing morbidity and mortality in late preterm and evade invasive procedures.

Objectives

1. To study the role of antenatal steroid in Respiratory distress in late preterm(34-36weeks)
2. To study the incidence of Respiratory Distress in late preterm born to mothers receiving an tenatal steroids in correlation to

- Gestational weeks (34,35,36 weeks)
- Number of late preterms requiring oxygen
- Number of late preterms requiring intubation and ventilation
- Number of deaths of late preterms due to respiratory morbidities

Materials and methods

Place of study

Patients who fulfill the inclusion and exclusion criteria coming to Department of Paediatrics at Shadan Institute of Medical Sciences

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Study design
Prospective case control study
Duration of study
October 2018 to august 2020
Study population
100 cases and 100 controls
Methodology
Inclusion criteria
1. All late preterm babies born between 34- 36 weeks
2. All late preterm babies whose mother has received antenatal steroid.
3. All late preterm babies whose mother has not received antenatal steroid

Exclusion criteria
1. Babies born <34 weeks and > 37weeks
2. Still born
3. Congenital anomalies
4. Respiratory distress due to cardiac causes or infections /sepsis.

Procedure
All the late preterm babies meeting the inclusion criteria were taken into the study. A pre-designed, pre-tested, semi structured and pre-coded proforma was used for recording all the findings. The questions were partially closed ended. After obtaining
Ethical clearance from the Institutional Ethical Committee, study was conducted. All the questions were explained in their colloquial language and all the doubts were cleared during completion of their questionnaire.
The questionnaire had the questions regarding the following:
1. Demographic information: name, gestational age, maternal complication,
2. Clinical data: administration of steroids, need for resuscitation, NICU admission.
3. Outcome of late preterm.

Data Entry and Analysis
The data was entered in Microsoft Excel 2010 version. Data was analyzed using Microsoft Excel 2010 and Epi Info 7.2.1.0 Descriptive and inferential statistical analysis were used in the present study. Results on continuous measurements were presented on Mean±SD (Min-Max) and results on categorical measurements were presented in Number (%). Significance was assessed at 5% level of significance. Chi-square test was used to assess the significance.

Ethical Clearance
Ethical clearance was obtained from the Institutional Ethical Committee, Shadan Institute of Medical Sciences, Hyderabad.

Results

Table 1: Gestational age (GA) at Delivery

GA at Delivery	Study Group	Control Group
Mean	34.58	34.39
St Dev	0.77	0.61
P Value	0.055	

The mean gestational age in the interventional group was 34.58 weeks (SD:0.77) compared to 34.39 weeks (0.61) in the control group with a P value of 0.055 signifying a non-significant difference.

Table 2: Reasons for Preterm Delivery

Reasons for Preterm Delivery	Study Group	Control Group	P value
Antepartum Hemorrhage	8	20	0.014 (higher in control group)
GDM	19	13	0.24 (NS)
PIH	29	20	0.138 (NS)
Preeclampsia	2	0	NA
PROM	32	29	0.644 (NS)
Severe Oligohydramnios	10	18	0.103 (NS)

The reasons for preterm delivery included antepartum hemorrhage in 8 and 20 mothers, gestational diabetes in 19 and 13, pregnancy induced hypertension in 29 and 20, preeclampsia in 2 and 0, preterm premature rupture of membranes in 32 and29, severe oligohydramnios in 10 and 18 mothers in study group and the control group respectively. The difference was non-significant except for slightly higher antepartum cases in control compared to the study group with a P value of 0.014.

Table 3: Birth weight

Birth weight	Study Group	Control Group
Mean	2.057	2.011
St dev	0.29	0.26
P value	0.249	

The birth weight was non-significantly different when either of the groups were compared. It was 2.057 kg (SD:0.29) in study group compared to 2.011 Kg (SD:0.26)in the control group. The P value was 0.249.

Table 4: APGAR score at 1min

APGAR-1	Study group	Control group
Mean	5.35	5.01
SD	1.10	1.23
P value	**0.041***	
Inference	Significantly higher in study group at 1 min	

The mean APGAR score at 1 minute was 5.35 in study group (SD:1.1) compared to 5.01 in control group (SD:1.23). The P value was significant at 0.041 at 95%confidence interval with a higher mean value in study group.

Table 5: APGAR score at 5min

APGAR-5	Study group	Control group
Mean	6.4	6.03
SD	1.09	1.33
P value	**0.03***	
Inference	Significantly higher in study group at 1 min	

The mean APGAR score at 5 minutes was 6.4 in study group (SD:1.09) compared to 6.03 in control group (SD:1.33). The P value was significant

at 0.03 at 95%confidence interval with a higher mean value in study group.

Table 6: Neonatal Outcome

Neonatal Outcome	Study Group	Control Group	Odds ratio	95% CI	P value
Neonatal resuscitation	26	40	0.527	0.289 to 0.9601	**0.0363***
NICU admission	15	27	0.47	0.235 to 0.96	**0.039***

26 neonates in study group required resuscitative measures compared to 40 in the control group. The Odd's ratio was 0.527 with significant P value of 0.0363 suggesting lower instance of neonatal resuscitation in study compared to the control group (95% confidence interval 0.289 to 0.9601). 15 neonates in study group required NICU admission compared to 27 in the control group. The Odd's ratio was 0.47 with significant P value of 0.039 suggesting lower instance of NICU admissionin study compared to the control group (95% confidence interval 0.235 to 0.96).

Table 7: Diagnosis in patients requiring resuscitative measures

	Study group	Control group
Transient tachypnoea of new born	11	12
Hyaline membrane disease	11	32
P value	**0.0422***	
Inference	Significantly higher incidence of HMD in control group	

11 subjects each in study group developed transient tachypnoea of new born (TTNB) and Hyaline membrane disease whereas in control group there were 12 neonates with TTNB and 32 with Hyaline membrane disease. The difference was significant with a significantly higher incidence of hyaline membrane disease in control with P value of 0.0422.

Table 8: Gender correlation with incidence of respiratory distress

	Study group		Control group		P value
	Male	Female	Male	Female	
TTNB	5	6	5	6	1
HMD	7	4	19	14	**0.031***

There was significant correlation between gender and respiratory distress. 5 males each and 6 females each had TTNB in study and control group respectively whereas7 and 19 males had HMD, and 4 and 14 females had HMD in study and control group respectively. The difference was non-significant with P value of 1 for TTNB and significant P value of 0.003 for HMD respectively, showing an increased incidence for HMD in male gender in control group

Table 9: Assisted Ventilation

Assisted Ventilation	StudyGroup	Control Group	Odds ratio	95% CI	P value
a) CPAP	3	4	0.74	0.16 to3.4	0.701
b) Mechanical ventilator	7	17	0.367	0.145 to0.9301	**0.0346***
c) Oxygen	12	23	0.4565	0.21 to0.978	**0.043***
rall interventions(a+b+c)	22	44	0.359	0.193 to0.664	**0.0011***

3 neonates in study group required CPAP compared to 4 in the control group. The Odd's ratio was 0.74 with non-significant P value of 0.701 suggesting non-significant difference of CPAP use in study compared to the control group (95% confidence interval 0.16 to 3.4). 7 neonates in study group required mechanical ventilation compared to 17 in the control group. The Odd's ratio was 0.367 with significant P value of 0.0346 suggesting lower instance of need for mechanical ventilation in study compared to the control group (95% confidence interval 0.145 to 0.9301). 12 neonates in study group required oxygen supplementation compared to 23 in the control group. The Odd's ratio was 0.4565 with significant P value of 0.043 suggesting lower instance of need for oxygen supplementation in study compared to the control group (95% confidence interval 0.21 to 0.978). 22 neonates in study group required some or other intervention compared to 44 in the control group. The Odd's ratio was 0.359 with significant P value of 0.0011 suggesting lower instance of need for some or other intervention in study compared to the control group (95% confidence interval 0.193 to 0.664).

Table 10: Neonatal death

Neonatal death	Study Group	Control Group	Odds ratio	95% CI	P value
Deaths	4	12	0.305	0.095 to 0.982	**0.0466***

3 neonates in study group died compared to 12 in the control group. The Odd's ratio was 0.305 with significant P value of 0.0466 suggesting significantly lower instance of neonatal deaths in study compared to the control group (95% confidence interval 0.095 to 0.982).

Discussion

Babies born between 34 and 36 weeks of gestation have, until recently, been considered sufficiently mature to be treated similarly to term infants. Whilst for many of these infant outcomes are good, it is now recognized that significant maturation occurs during the last weeks of gestation, placing late preterm infants at increased risk of adverse health outcomes in the neonatal period and beyond [1][2]. Late preterm delivery interrupts normal in utero respiratory development and relative immaturity is compounded by associated adverse perinatal factors. These include increased rates of caesarean delivery [3], and increased rates of intrauterine growth retardation [4] and associated maternal factors, including hypertensive disorders, diabetes and smoking [5][6].

The current study was conducted to evaluate the utility of using steroids in mothers delivering between 34 to 36 weeks of gestational age (late preterm births) and neonatal outcomes such as need for resuscitation, NICU admission, APGAR scores, need for interventions such as oxygen supplementation, CPAP and mechanical ventilation. In addition, neonatal morbidity was also evaluated.The study was double group, randomized study with interventional group (study group) and the comparator (control group) comprising of 100 patients each. The patients were randomly assigned to either of the group, however in case the delivery was inevitable before giving steroid injection the patients were invariably assigned to the control group. The steroid injections comprised of either dexamethasone or betamethasone with a maximum of 2 doses given in the study group.

Due consent was obtained from the patients satisfying the inclusion criteria of age above 18 years, Gestational age between 34 to 36 weeks, willing to comply with the study protocol and they were included in the study. Patients aged less than 18 years, gestational age

beyond 36 completed weeks and less than 34 weeks and those unwilling to give a consent were not included in the study.

Gestational age

The mean gestational age in the interventional group was 34.58 weeks (SD:0.77) compared to 34.39 weeks (0.61) in the control group with a P value of 0.055 signifying a non-significant difference. Recent studies comparing the neonatal outcomes of late preterm of gestational age 34 to 36 weeks with term infants above 37 weeks confirm late preterm infants to have higher rates of respiratory morbidity [7][8] and to be more likely to require respiratory support or surfactant therapy [9][10]. More recently, passive respiratory mechanics and tidal breathing parameters were compared in 31 healthy 33-36-week infants at term-equivalent age and 31 term infants within 72 hours of birth. The late preterm infants had decreased respiratory compliance, decreased tidal ratio and increased respiratory resistance [11]. Hence, gestational age plays a vital role in respiratory development and post birth respiratory morbidity.

Reasons for preterm births

The reasons for preterm delivery included antepartum hemorrhage in 8 and 20 mothers, gestational diabetes in 19 and 13, pregnancy induced hypertension in 29 and 20, preeclampsia in 2 and 0, preterm premature rupture of membranes in 32 and29, severe oligohydramnios in 10 and 18 mothers in study group and the control group respectively. The difference was non-significant except for slightly higher antepartum cases in control compared to the study group with a P value of 0.014.Preterm delivery may be spontaneous or indicated in response to adverse maternalor fetal conditions. Spontaneous premature deliveries continue to outnumber those attributable to obstetric indications, particularly after 34 weeks of gestation where spontaneous deliveries account for 80% of births; [12] nevertheless, prematurity due to obstetric intervention is increasing [13]. Common reasons for indicated preterm births include pre-eclampsia or eclampsia, and intrauterine growth restriction. Births that follow spontaneous preterm labour and PPROM—together called spontaneous preterm births—are regarded as a syndrome resulting from multiple causes, including infection or inflammation, vascular disease, and uterine over distension.

Women with diabetes have higher rates of obstetric complications such as stillbirth and pre-eclampsia and are therefore more likely to be electively delivered earlier than women without diabetes [14].

Birth weight

The birth weight was non-significantly different when either of the groups were compared. It was 2.057 kg (SD:0.29) in study group compared to 2.011 Kg (SD:0.26)in the control group. The P value was 0.249.

APGAR score

The mean APGAR score at 1 minute was 5.35 in study group (SD:1.1) compared to 5.01 in control group (SD:1.23). The P value was significant at 0.041 at 95% confidence interval with a higher mean value in study group.

The mean APGAR score at 5 minutes was 6.4 in study group (SD:1.09) compared to 6.03 in control group (SD:1.33). The P value was significant at 0.03 at 95%confidence interval with a higher mean value in study group.

Though survival rates of infants born in the late preterm period are within 1% of those born at term [148], these infants are more likely have low APGAR scores than their term counterparts [15]. However, on contrary, another retrospective study showed no significant effect of Antenatal corticosteroids on APGAR scores, umbilical cord gases, infections, or respiratory morbidity [16].

Neonatal resuscitation and NICU admission

26 neonates in study group required resuscitative measures compared to 40 in the control group. 15 neonates in study group required NICU admission compared to 27 in the control group. The Odd's ratio was 0.47 with significant P value of 0.039 suggesting lower instance of NICU admission in study compared to the control group (95% confidence interval 0.235 to 0.96). A prospective cohort study of preterm twins showed that antenatal corticosteroids reduced need for NICU admissions. In 2005, the large Antenatal Steroids for Term Caesarian Section (ASTECS) trial, a non-blinded RCT of ACS prior to elective caesarean section after 37 weeks, reported that infants exposed to ACS had lower rates of NICU or special care admission and were less likely to require resuscitation/ventilation at birth. The number needed to treat (NNT) to prevent one admission to NICU/special care unit was 37 and the rates of both RDS or TTN appeared to be reduced to an equivalent extent [17].

Gender and incidence of respiratory distress

There was significant correlation between gender and respiratory distress. 5 males each and 6 females each had TTNB in study and control group respectively whereas 7 and 19 males had HMD, and 4 and 14 females had HMD in study and control group respectively. The difference was non- significant with P value of 1 for TTNB and significant with P value of 0.003 for HMD respectively, showing an increased incidence for HMD in male gender in control group.

Need for interventions

3 neonates in study group required CPAP compared to 4 in the control group. The Odd's ratio was 0.74 with non-significant P value of 0.701 suggesting non-significant difference of CPAP use in study compared to the control group (95% confidence interval 0.16 to 3.4). 7 neonates in study group required mechanical ventilation compared to 17 in the control group. The Odd's ratio was 0.367 with significant P value of 0.0346 suggesting lower instance of need for mechanical ventilation in study compared to the control group (95% confidence interval 0.145 to 0.9301). 12 neonates in study group required oxygen supplementation compared to 23 in the control group 22 neonates in study group required some or other intervention compared to 44 in the control group. Multiple randomized trials have demonstrated reduction in the rate of neonatal respiratory distress syndrome (RDS) [18,19], with additional benefits, including reduction in the rates of intraventricular hemorrhage (IVH) and necrotizing enterocolitis (NEC), and reduced hospital stay for infants upon use of antenatal corticosteroids. Recent evidence has found that infants born in the late preterm period or via non-labour caesarean section in the early term period suffer from higher rates of morbidity than their counterparts born via either non-labour caesarean section after 39 weeks or planned vaginal delivery after 37 weeks [20], and that the rates of these complications can be reduced by administration of Antenatal corticosteroids [21].

Neonatal deaths

3 neonates in study group died compared to 12 in the control group. The Odd's ratio was 0.305 with significant P value of 0.0466 suggesting significantly lower instance of neonatal deaths in study compared to the control group (95% confidence interval 0.095 to 0.982).. The results showed ACS to be associated with a significant reduction in the primary outcome, which included stillbirth and neonatal death within 72 h (neither of which occurred) and a composite endpoint of a need for respiratory support in the first three days of life (for the latter RR: 0.67; 95% CI: 0.53–0.84; P < 0.001). Our study matched with studies of other workers as observed from the above data.

Limitations

1. The study sample was less to extrapolate to regional and national trends.
2. The study was not blinded that could lead to bias.
3. The cost-effectiveness of using steroids on maternal and neonatal morbiditywas not evaluated.
4. Long term follow up was not performed in the patients.
5. Use of other interventions, treatment of neonatal morbid conditions may have an impact on neonatal outcomes leading to confounding results.

Conclusion

Based on findings of our study:

i. There was lesser need for neonatal resuscitation and NICU admissions instudy group.
ii. There was significantly higher incidence of neonatal hyaline membranedisease in the control group
iii. The mean APGAR score was significantly better in study group at 1minute and 5 minutes.
iv. There was lesser need for interventions such as oxygen

supplementations, CPAP use, mechanical ventilation in study group compared to the control group. The values were significant.

v. The neonatal deaths were significantly lower in study group.

vi. Steroids injections of either betamethasone or dexamethasone given to mothers expecting a preterm delivery between 34 to 36 weeks may have a beneficial effect on neonatal outcomes especially the respiratory parameters.

vii. We suggest use of antenatal steroids in prior to expected preterm birthsbased on finding of our study.

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