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Maternal and fetal outcome of administration of corticosteroids in late preterm period

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Abstract
The role of antenatal corticosteroids before 34 weeks has been extensively studied and proven to be effective. However of the 15 million preterm births annually worldwide an important segment, late preterm births that is birth between 34 weeks to 36.6 weeks remains unaddressed. While it is true that the incidence of respiratory complications is less in these babies the morbidity is still higher than term infants. The role of antenatal corticosteroids here is controversial as there needs to be a balance between respiratory complications and long term morbidity associated with antenatal corticosteroids.
Background: Late preterm birth comprise 72% of preterm births yet adequate studies regarding this period are still lacking. We conducted this study at MGM medical College and Hospital, A tertiary care centre.
Objectives: To determine effectiveness of antenatal corticosteroids in late preterm period.
Methods: A total of 50 patients with gestational age between 34.1to 36.6 weeks were included in this study, they were divided into cases and controls of 25 patients each. Case group received antenatal corticosteroids and control group did not receive corticosteroids. Maternal and neonatal outcomes were then studied.
Results: There was a significant reduction in neonatal respiratory morbidity in the case group over a short term period.
Conclusion: Antenatal corticosteroids are effective in late preterm period in reducing short term respiratory morbidity however the possibility of long term effects should be weighed against the benefits. Decision to administer steroids should be made on a case by case basis.

Keywords: Late preterm, antenatal corticosteroids, Betamethasone, Respiratory distress syndrome

Introduction
Preterm birth is a major cause of neonatal morbidity and mortality all over the world [1]. Preterm babies are prone to a number of complications such as respiratory, gastrointestinal, intracranial hemorrhage, this occurs primarily due to immaturity of organ systems [2]. The role of antenatal corticosteroids in preterm labour has been proven beyond a doubt. However most studies have only evaluated the role of corticosteroids < 34 weeks of gestation. A majority of preterm births however is constituted by late preterm birth that is between 34 to 36.6 weeks. These neonates are at increased risk of respiratory complications and intensive care admissions. Despite occupying such a large proportion of preterm deliveries all over the world adequate studies regarding role of corticosteroids in this subgroup are still lacking. The risk- benefit ration of administering corticosteroids during this time period is still under evaluation. The aim of this study is to determine whether antenatal corticosteroids during late preterm period helps in reducing neonatal complications and intensive care admissions.

Material Methods
This study was carried out at MGM Medical College and Hospital, Department of Obstetrics and Gynecology, Navi Mumbai over a period of two years Nov 2018 to Oct 2020. After due permission from the institutional ethics committee 50 antenatal patients between gestational age 34-36.6 weeks likely to deliver preterm were included in the study and divided equally after randomization into Group A- Cases and Group B- Controls. Group A- received 2 doses of Betamethasone 12mg 12 hours apart and Group B- No placebo was given. Both groups were matched for maternal age, gestational age, parity and comorbidities.

Eligibility Criteria

- All patient with gestational age 34.1- 36.6 weeks likely to be delivered before completion of 37 weeks.

Exclusion Criteria

- All patients with gestational age not known or confirmed by ultrasound
- Patients having co morbidities such as chorioamnionitis in which administration of corticosteroids is contraindicated.
- Patients previously administered corticosteroids.
- Patients with multiple gestation.

Patients in this study were included irrespective of mode of delivery. Post-delivery neonates were monitored for duration of NICU stay, incidence of respiratory distress (in the form of grunting, retractions and nasal flaring) incidence of necrotizing enterocolitis, incidence of intraventricular hemorrhage, incidence of transient tachypnea of newborn, APGAR score, need for oxygen therapy (in the form of oxygen by hood and supplemental nasal cannula) need for surfactant, artificial ventilation and incidence of neonatal hypoglycemia.

Statistical Analysis

The study parameters were represented as their mean $\pm$ SD. The significance threshold of p value was set at 0.05. All analysis was carried out by using statistical analysis software.

Results

Comparison of demographic characteristics

Overall there was no statistical difference in between the two groups when compared for maternal age, gestational age, parity, mode of delivery and comorbidities.

Table 1: Comparison of demographic characteristics of group A and B

	Group A	Group B	P value
Mean Maternal Age	26.52	25.16	0.37
Mean Gestational Age	35.60	35.52	0.72
Co- Morbidities	16	12	0.39
Parity			
Primipara	16	13	**0.57**
Multipara	9	12	
Mode of Delivery			
LSCS	12	10	**0.77**
Vaginal	13	15	

No difference was observed between the study groups with regards to maternal complications like incidence of infections (4% vs 0%; p-1.0), fever (8% vs 4%; p-1.0) and wound infections (4% vs 0%; p-1.0).

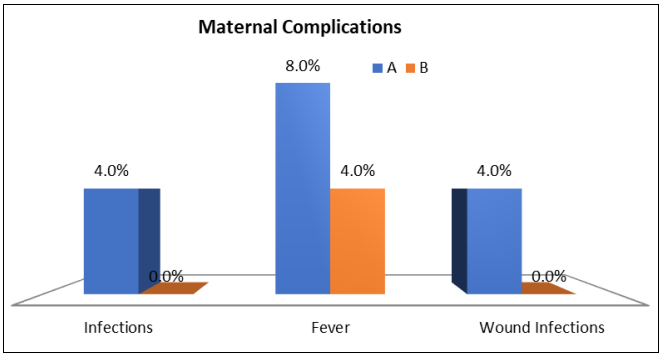

Fig 1: Distribution of study groups as per maternal complications

Distribution of study groups as per incidence of low birth weight

Incidence of low birth weight in present study was 64% in group A and 72% in group B (p- 0.76).

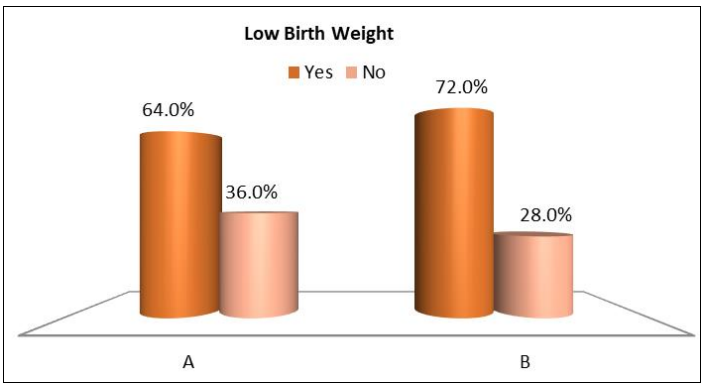

Fig 2: Comparison of low birth weight babies between case and control group (Low birth weight was taken as 2.5kg)

Distribution of study groups as per incidence of low birth weight

Comparison of Neonatal Outcome

Incidence of low APGAR at 5 minutes was significantly more in group given standard care as compared to corticosteroid group (60% vs 8%; p<0.01).

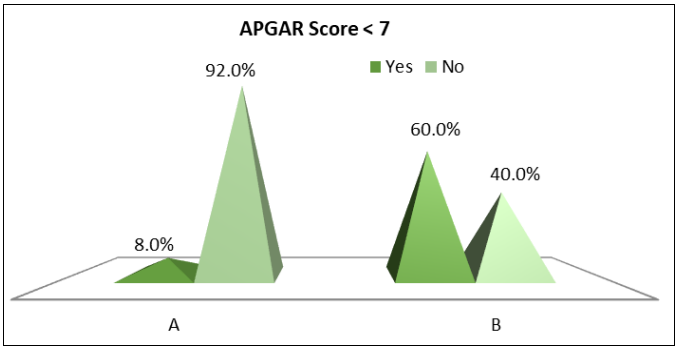

Fig 3: Distribution of study groups as per APAGAR score

Distribution of study groups as per neonatal complications

Table 2: Comparison of neonatal complications between group A and B

Neonatal Complications	Group		Total	p-value
	A	B		
Hypoglycemia	5	5	10	1.00
	20.0%	20.0%	20.0%	
Respiratory Distress	3	18	21	<0.01
	12.0%	72.0%	42.0%	
Transient Tachypnoea	2	18	20	<0.01
	8.0%	72.0%	40.0%	
RDS (Hyaline Membrane Disease)	0	3	3	0.07
	0.0%	12.0%	6.0%	
IVH	0	1	1	0.31
	0.0%	4.0%	2.0%	
Neurological Complications	0	0	0	NA
	0.0%	0.0%	0.0%	
NEC	0	0	0	NA
	0.0%	0.0%	0.0%	

Neonatal complication like Respiratory distress (in the form of grunting, retraction and nasal flaring) (12% vs 72%), transient

tachypnoea (8% vs 72%) were significantly less in corticosteroid group as compared to control group. The number of cases with respiratory distress syndrome requiring surfactant were slightly higher in Group B (0% vs 12%) however this difference was not statistically significant (p=0.07). While no difference was observed between complications like hypoglycaemia (20% each) and IVH (0% vs 4%). There was no case of necrotising enterocolitis in our study.

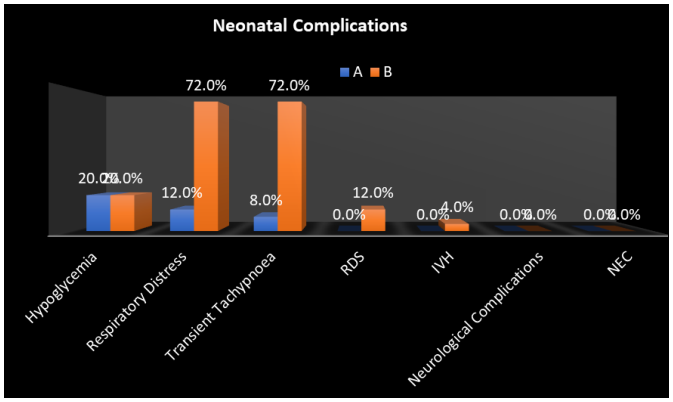

Fig 4: Distribution of study groups as per neonatal complications

Table 3: Distribution of study groups as per neonatal interventions

Neonatal Interventions	Group		Total	p-value
	A	B		
Need for Respiratory Support (<72 hours)	2	19	21	<0.01
	8.0%	76.0%	42.0%	
Oxygen Therapy	2	15	17	<0.01
	8.0%	60.0%	34.0%	
Surfactant	0	3	3	0.07
	0.0%	12.0%	6.0%	
NICU Stay	7	21	28	<0.01
	28.0%	84.0%	56.0%	

Requirement of interventions like respiratory support in the form of CPAP or positive pressure ventilation (8% vs 76%; p<0.01), oxygen therapy in the form of supplemental nasal cannula and oxygen by hood (8% vs 60%; p<0.01) were significantly less corticosteroid group as compared to control group. No baby required mechanical Ventilation. Surfactant requirement was also less in the in test group (0% vs 12%) however it was not statistically significant (p=0.07). Requirement of NICU stay was also lower in these new-borns (28% vs 84%; p<0.01).

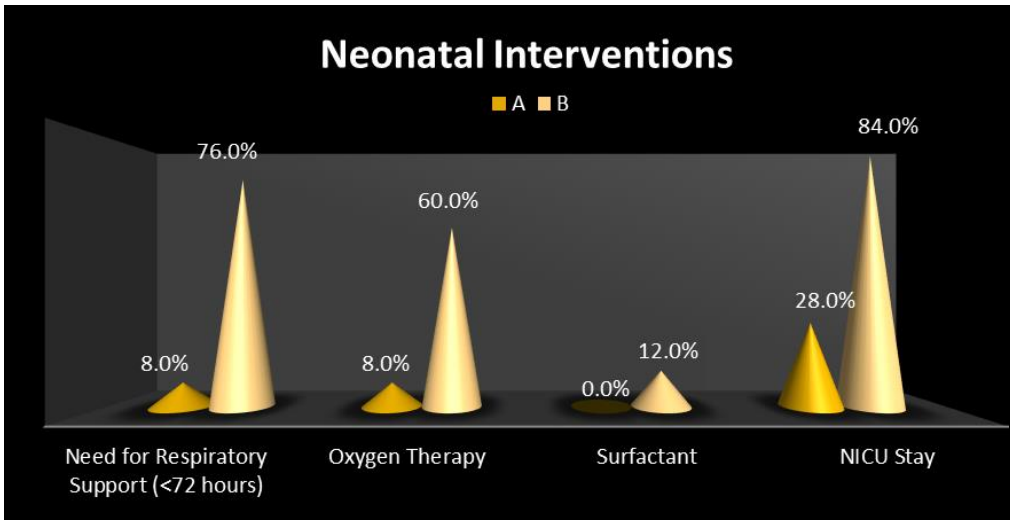

Fig 5: Distribution of study groups as per neonatal interventions

Table 4: Distribution of study groups as per mean NICU stay

Variables	Group	N	Mean days of stay	SD	p- value
NICU Stay	A	7	3.71	1.38	<0.01
	B	21	5.92	2.38	

Mean NICU stay of babies was significantly higher in control group as compared to study group (5.92 vs 3.71 days; p<0.01).

Discussion

Numerous respiratory complications are associated with pre-term births which includes: respiratory distress syndrome, chronic lung disease and BPD, etc. [3]. In comparison to term infants, infants born late preterm are also at increased risk for neonatal intensive care unit (NICU) admission, hospital readmission and have longer hospital stay. They also have greater predisposition for respiratory morbidities [3].

One of the most important causative factor for neonatal morbidity in pre-terms is Neonatal Respiratory distress syndrome. This is even true for infants who are born at late preterm (between 34 weeks to 36 weeks of gestation) as they are also more likely to have greater respiratory complications than infants born at term [4].

Surfactant deficiency as well as immaturity in other organs including lungs are the known causes for respiratory failure in pre-term babies. Increased length of gestation which reflects improved maturity of organ systems after preterm birth improves neonatal survival [4].

Prophylactic corticosteroids in these singletons preterm a pregnancy has shown to accelerate lung maturation and reduces the incidence of RDS [5]. Due to the aforementioned reasons, two doses of betamethasone or 4 doses of dexamethasone are currently recommended in women at risk of preterm birth (between 24 weeks and 33.6 weeks of gestation) within seven days [6, 7].

However, the administration of corticosteroids at or more than 34 weeks of gestation is still controversial [5-7].

Recently, ACOG recommended antenatal corticosteroids to be given for women with likelihood of delivering late premature i.e.> 34 weeks gestation but not for women undergoing elective CS at term; [7] whereas as per RCOG, antenatal corticosteroids should be advised to all women with elective c-section before 38.6 weeks of gestation [6].

If antenatal corticosteroids works towards improvement of respiratory function, it is quite obvious that provide continued benefit across the spectrum of preterm, and potentially early term period. It has been postulated that corticosteroids may be effective at later gestational ages not only because of an increase in surfactant production from type II alveolar cells or acceleration in lung structural development reducing the incidence of classic RDS, but also by increasing expression of epithelial sodium channels (ENaC) which allow the alveoli to convert from active fluid secretion to sodium and fluid absorption with subsequent reduction of the fetal lung fluid. [8]

In present study, we aimed to evaluate the effectiveness of administration of corticosteroids in late preterm babies and its impact on fetal morbidity and NICU stay. A total of 50 cases between gestational age of 34- 36.6 weeks were taken in the current study. Eligible patients were randomly allocated into two groups:

Group A- where Betamethasone 12 mg IM 2 doses 24 hours apart was given and;

Group B- where standard care was given.

The mean age in study group was 26.52 and 25.16 in control group (p-0.37 while mean gestation age was 35.6 and 35.52 weeks in group A and group B respectively (*p*-0.72). Overall 58% cases were primi-para and 42% were multi-para. Incidence of caesarean delivery was 44%. No difference was observed between the study groups with regards to age, gestation age, associated co-morbidities and mode of delivery (p>0.05). Also, no difference was observed between the study groups with regards to gender of baby, birth weight and maternal complications like incidence of infections (4% vs 0%; p-1.0), fever (8% vs 4%; p-1.0) and wound infections (4% vs 0%; p-1.0).

We observed that incidence of low APGAR at 5 minutes was significantly more with controls (60% vs 8%; p<0.01). Respiratory distress was monitored in the form of grunting, retractions and nasal flaring and it was noted in 12% cases of corticosteroid group as compared to 72% in control group. Other respiratory complications like transient tachypnoea (8% vs 72%) and respiratory distress syndrome (0% vs 12%) were also significantly less in corticosteroid group as compared to control group. Similarly, requirement of interventions like respiratory support in the form of CPAP or PPV (8% vs 76%; p<0.01), oxygen therapy in the form of nasal cannula and oxygen by hood (8% vs 60%; *p*<0.01) and surfactant (0% vs 12%; p-0.07) were significantly less corticosteroid group as compared to control group. Requirement of NICU stay was also significantly lower in these new borns (28% vs 84%; *p*<0.01). Mean NICU stay of babies was also significantly more in control group as compared to study group (5.92 vs 3.71 days; *p*<0.01).

Various other studies are also in accordance with resent study results. The ASTECS study reported significant reduction of over half (54%) in admissions to NICU for respiratory disorders. [9]

Balci O *et al*., [10] studied hundred pregnant women, susceptible to have preterm delivery i.e. between 34th to 36th weeks of pregnancy. Half of the patients did not receive betamethasone (controls), while 12 mg betamethasone in a single dose is administered to other half (cases). Better Apgar scores were reported in babies who received steroids as compared to controls (*p*<0.01). Resuscitation was required in 16 (32%) neonates of control group as compared to 7 (14%) neonates of cases (p - 0.032). RDS was observed in 16% new borns of controls as compared to 4% of babies of case group (p-0.046).

Ahmed MR *et al*., [11] studied the overall incidence of respiratory distress among cases and controls, similar to our study. They observed the rates as 7.9% in steroid group and 23% in control group. Trasient Tachyponea of New-born was the main morbidity seen in 7% of cases versus 19.6% of controls. They also observed a significantly lower incidence of mild and moderate degrees (7 and 0.9%, respectively) of respiratory distress in the case group as compared to controls (17 and 5.3%). They observed that babies who were born between 37-37(+6) weeks garnered maximum benefit from the intervention.

In another similar study, singleton pregnancies at 34 weeks 0 days to 36 weeks 5 days, with probability for delivery during the late preterm period (up to 36 weeks 6 days) was observed by Gyamfi-Bannerman C *et al*. [12] Neonatal composite of treatment in the first 72 hours or stillbirth or neonatal death within 72 hours after delivery were taken as the end result. This occurred in 11.6% new-borns in the steroid group as compared to 14.4% in the control group (p-0.02). Respiratory complications, TTN, BPD and surfactant use also occurred significantly less frequently in steroid group. The incidence of neonatal sepsis or chorioamnionitis was however comparable (*p*>0.05).

The Neonatal Intensive Care admission rate for respiratory morbidity as observed in the study by Nada AM *et al*., [13] was significantly lower in the steroid group as compared with controls [1.6% vs 3.9%; *p*<0.05]. The study observed that antenatal administration of steroid leads to almost two and half fold reduction in the risk of Neonatal Intensive Care admission in view of respiratory morbidity (p<0.05).

A meta-analysis of similar studied comparing role of steroids in early pre-term was conducted by Saccone G *et al*. [14] They reported a significantly lower risk of RDS, transient tachypnea of the new born, use of surfactant and mechanical ventilation along with a higher APGAR scores compared with controls in the infants of mothers who received antenatal steroids at ≥34 weeks had.

Long term effects of corticosteroids into adulthood require further research which is currently beyond the scope of this study.

Thus to summarize, antenatal steroids in late pre-term neonates tend to reduce respiratory morbidity and decreases requirement of NICU admissions. Present study thus recommend single course of corticosteroids to be administered to women who are at risk of delivering in late preterm period.

Conclusion

In present study, we observed that antenatal steroids in late pre-term neonates tend to reduce respiratory morbidity and decreases requirement of NICU admissions. We thus conclude that a single course of corticosteroids (two 12 mg doses of betamethasone given intramuscularly 24 hours apart) is advisable for women at risk of imminent late preterm delivery at 34-36.6 weeks of gestation.

Conflict of Interest

Not available

Financial Support

Not available

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