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# Audit of antenatal corticosteroids for fetal maturation in preterm labour

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**Abstract**
**Background:** Preterm birth complications are the leading cause of neonatal morbidity and mortality as well as under-five (child) mortality. India has the highest number of Preterm births as well as neonatal deaths due to prematurity. One of the most important antenatal therapies available in Preterm labour is administration of corticosteroids for fetal maturation. Although data exists from western countries regarding its usage, efficacy and safety, the data from Indian centers is sparse and therefore, we did a prospective observational study in an attempt to identify the same in our country.
**Method:** A prospective observational study with 182 pregnant women between 23 0 / 7 - 36 6 / 7 weeks in preterm labour were obtained from a teaching hospital in a metropolitan city.
**Results:** Our study showed that 1) the antenatal steroid coverage in our hospital was 59.3% as compared to a coverage of 90% in well developed countries. 2) Out of the total patients, only 27.78% received the complete optimum course. 3) Although the Ministry of Health & Family Welfare of India recommend Injection Dexamethasone as the drug form to be used, 89.81% received Betamethasone as the drug form. 4) There was reduction in the risk of developing RDS, need for respiratory support, surfactant and inotrope which was statistically significant in age group 28 0/7 -31 6/7 weeks of gestation. Also, neonates less than 32 weeks receiving complete course showed significant reduction in neonatal death as compared to those who could not complete the course. 5) There was no evidence of any maternal or neonatal complications.
**Conclusion:** Antenatal corticosteroids have a coverage rate of 59.3% with Betamethasone as the most commonly used drug form. Maximum efficacy was noted in gestational age group 28-32 weeks with no complications.

**Keywords:** Preterm labour, antenatal corticosteroids (ACS), RDS (respiratory distress syndrome), betamethasone, dexamethasone

## Introduction

Preterm labour is defined as the labour which starts before 37th completed weeks of gestation (<259 days) counting from the first day of last menstrual period. Preterm infants are those who are delivered before 37 completed weeks [1]. The burden: Preterm births account for approximately 70% of neonatal deaths and 36% of infant deaths as well as 25-50% of cases of long-term neurological impairment in children [2].

India has the highest number of Preterm births as well as neonatal deaths due to prematurity. Out of an estimated 2.6 crore live births in India each year, 35 lakh babies are born Preterm and out of these 3.03 lakh babies (approximately 10%) die due to complications of Preterm birth. Several survivors face a lifetime of disability including learning, hearing and visual disabilities. It is a risk factor in at least 50% of all neonatal deaths and is the second most common cause of death (after pneumonia) among children under the age of five [3].

The various therapies available in the management of Preterm labour are antenatal corticosteroids, tocolysis, progesterone, magnesium sulfate for neuro-protection and antibiotics in cases of premature rupture of membranes or established Preterm labour of which antenatal corticosteroids is one of the most important antenatal therapies available.

According to Cochrane review, the administration of ACS decreases the risk of neonatal morbidity and mortality by reducing the severity and incidence of respiratory distress syndrome by 34 percent, intraventricular haemorrhage by 46 percent, necrotizing enterocolitis by 20 percent, intensive care admissions by 20 percent and death by 31 percent amongst babies born preterm [4].

In India, antenatal steroid coverage for eligible mother in Preterm labour in Government sector hospitals is estimated to be 20-40%. In private sector hospitals in India, it is about 80%.

Therefore, there is an urgent need to devise strategies to address this key issue. [5] Therefore, it would be important to know the coverage of ACS from our region of India, especially through a teaching hospital. Short time gap available for steroid administration to delivery, failure to give referral shot of steroid, lack of knowledge to give steroid could be attributable to the poor coverage of antenatal corticosteroids [6].
Therefore, we intend to study the proportion of patients receiving ACS, its safety and efficacy in our hospital amongst those who are in preterm labour both established as well as suspected preterm labour.

## Materials and Methods

This Prospective Observational study was conducted among pregnant women admitted in the hospital with gestational age between 23 0/7 weeks- 36 6/7 weeks in established or suspected preterm labour and delivered within 7 days of having the same in a teaching hospital attached to a medical college in a metropolitan city. The study was carried from March 2019-September 2020.
Inclusion criteria:
Pregnant women with gestational age between 23 0/7 weeks – 36 6/7 weeks in established or suspected preterm labour and delivered within 7 days of having the same.
Exclusion criteria:

- Pregnant women in preterm labour with gestational age less than 23 weeks and gestation age above 36 6/7 weeks.
- Steroids when given for prophylactic reasons i.e when steroids are given for the risk factors but the patient is not in preterm labour such as Multiple pregnancy, Preterm Premature Rupture of Membranes, participants conceived after IVF and any other reasons.
- Any known major fetal structural or chromosomal abnormalities.
- One prior steroid course given.
- Women in preterm labour who decline enrolment

Sample size: Sample size was calculated using PS sample size calculator and using two proportions of the study by G.C. Liggins *et al*. [7] the total sample achieved after final calculations was 182.
Informed Consent & ethical approval: Taken by proper explanation in local language when women got admitted in the postnatal ward after delivery. This study was conducted after proper permission from ethical committee.

### Study procedure

For the purpose of study, we have defined established preterm labour as pregnant women between 23 0/7 weeks - 36 6-7 weeks and with Regular uterine contractions with or without pain, 4 contractions in every 20 minutes and cervical Dilatation (> 1 cm) and effacement (80%) of the cervix or improvement in cervical dilatation and effacement on serial examinations. For purpose of study, we define Suspected preterm labour as when such women complaint of symptoms of pelvic pressure, backache, abdominal pain, vaginal discharge or bleeding without the above cervical changes.
Also, for the purpose of study we have categorized Preterm birth as:

- Extremely preterm – less than 28 weeks
- Very preterm -28 0/7 weeks to 31 6/7weeks
- Moderate preterm- 32 0/7 to 33 6/7 weeks
- Late preterm - greater than 34 weeks
- We have defined complete dosing as
- Betamethasone - 2 doses of 12 mg each given IM 24 hours apart
- Dexamethasone - 4 doses of 6 mg each given IM 12 hours apart.

### Data collection

Participants fulfilling the above inclusion and exclusion criteria were enrolled after taking their written consent after their preterm delivery in the postnatal ward. Data for the CRF was captured from the indoor case papers (maternal and neonatal) noting the participant and her neonate's progress and treatment in the wards till discharge from the hospital.

### Data analysis

All the data was entered in the excel sheet. Data was summarized using proportions, percentages and calculating relative risk. Kruskal Walli's test was also used to compare neonatal outcome. p value of <0.05 was considered significant. (Windows 7, Graph pad, software, San Diego, California USA).

## Results

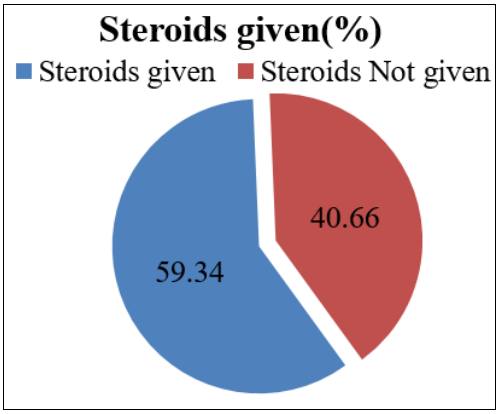


**Fig 1:** Received Antenatal Corticosteroids

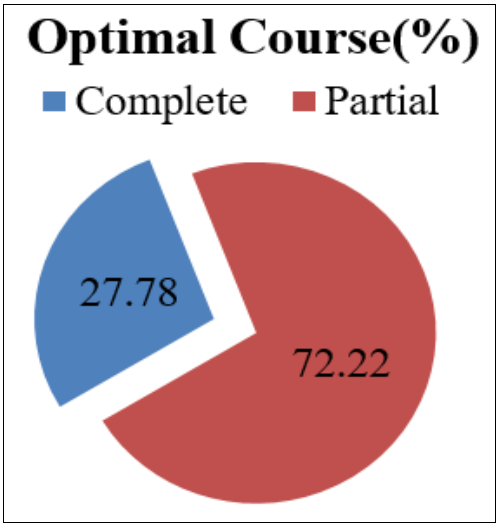


**Fig 2:** Received optimal (complete) course

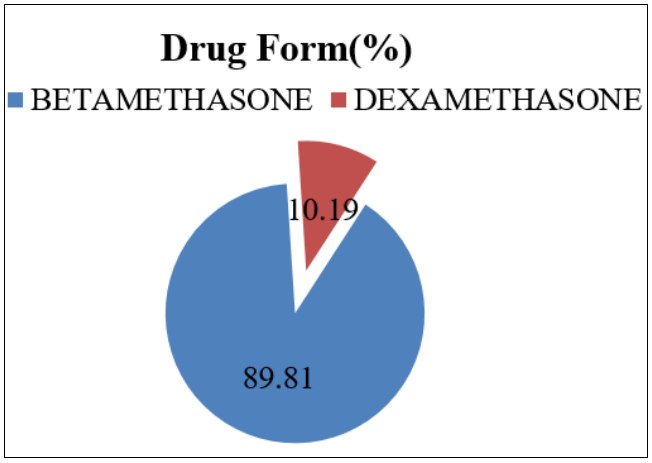


**Fig 3:** Drug from evaluation

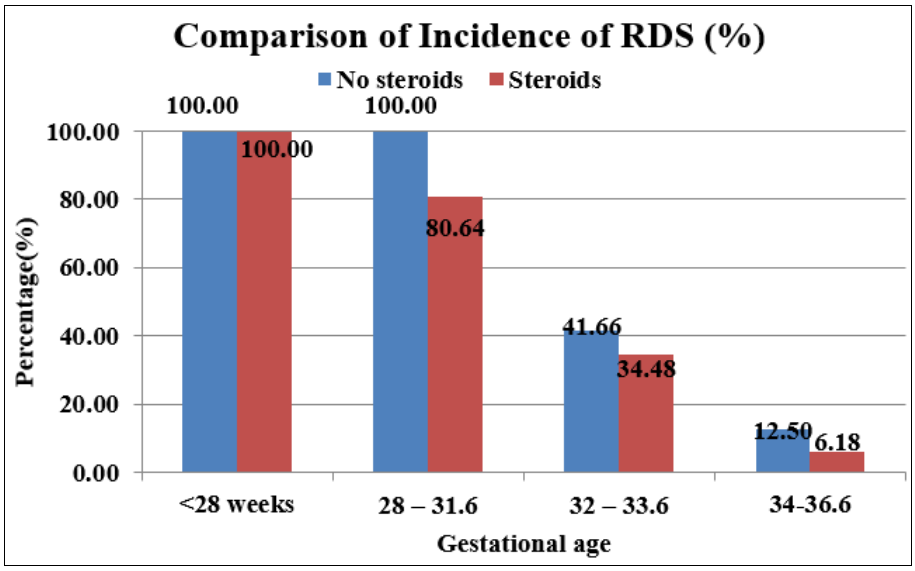


**Fig 4:** Comparison of incidence of RDS between patients who did not receive steroids versus patients who received steroids

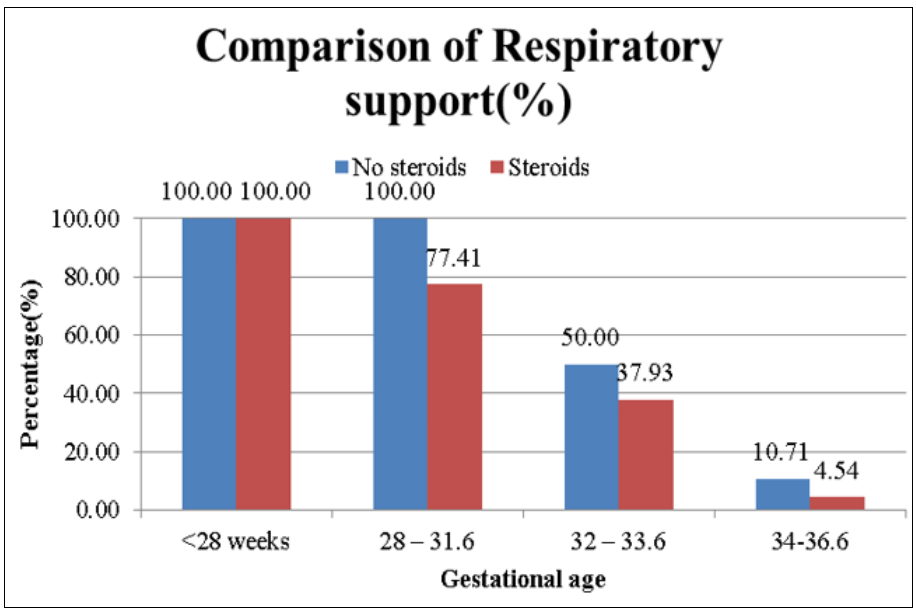


**Fig 5:** Comparison of need for respiratory support between patients who did not receive steroids versus patients who received Steroids

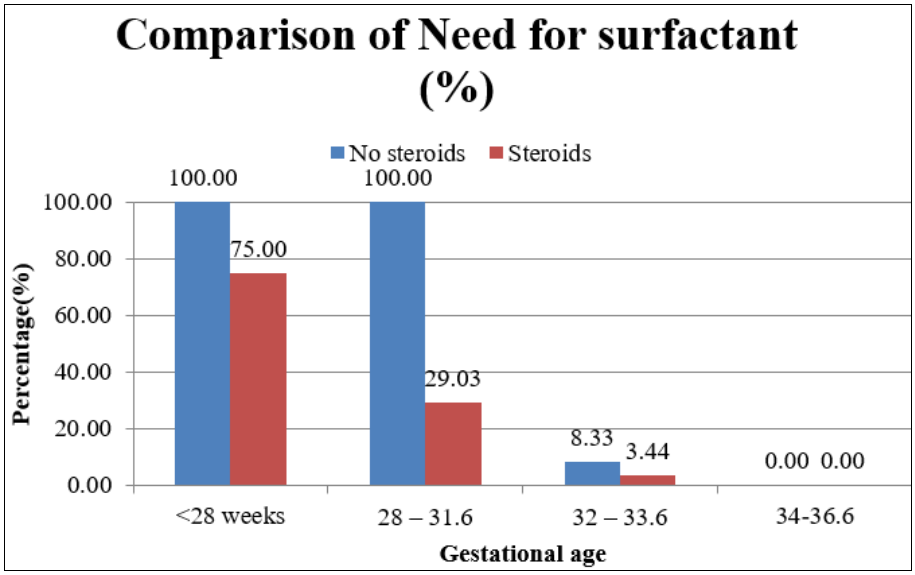


**Fig 6:** Comparison of Need for surfactant between patients who did not receive steroids versus patients who received Steroid

## Discussion

In our study, 182 participants were obtained from a teaching hospital affiliated to a medical college in a metropolitan city in a duration of 18 months from March 2019 to September 2020. It is a prospective observational study done to audit the use, efficacy and safety of ACS in our population.

The first observation of our study suggests that out of 182 patients who came in preterm labour, 108 patients received a course of antennal corticosteroids (59.3% coverage). Out of the 74 patients who did not receive steroids, a majority of 57 patients (77% patients) were above 34 weeks of gestation (Figure 1)

Thus in patients with gestational age of less than 34 weeks the coverage of ACS was (64 out of 82 patients that is 78%). However, in patients with gestational age more than 34 weeks the coverage was (44 out of 100 patients that is 44%). This may be seen due to the debate in current medical literature and thereby a dilemma amongst the consultants regarding the use of antenatal corticosteroids in patients with gestational age of more than 34 weeks.

The risk of potential harms such as neonatal hypoglycemia in the short term and the adverse neurodevelopmental effects in the long term may outweigh the benefit of reduction in rates of (TTN) which is a transient and treatable problem. Hence as a result of the controversial recommendations there is a dilemma in its use between our practitioners in our population in this gestational age group.

The rest 17 patients (27% patients) were less than 34 weeks and could not be given corticosteroids as they approached the hospital very late in an advanced stage of labour and delivered shortly. Short-time gap available for steroid administration to delivery, failure to give referral shot of steroid, lack of knowledge to give steroid could be the reasons behind the poor coverage of antenatal steroid. Increasing awareness amongst the medical and paramedical staff about antenatal corticosteroids administration at peripheral level should increase the rate of referral shot of steroids which should further reduce the neonatal mortality in India.

It is also observed that 108 patients who received steroids, only 30 patients (27.78%) patients received a complete course of steroids that is 2 doses of Injection Betamethasone 12mg each given Intramuscularly 24 hours apart or 4 doses of Injection Dexamethasone 6mg each given intramuscularly 12 hours apart. The rest (72.22%) delivered either within 48 hours of starting the steroid course or after 7 days of completing the steroid course and hence did not receive the complete optimum course (Figure 2).

In the present study, out of the 108 patients who received antenatal corticosteroids, 97 patients that is (89.81%) patients received Betamethasone as the drug form and only 11 patients (10.19%) patients received Dexamethasone as the drug form (Figure 3). This suggests the lack of knowledge amongst the consultants as to the recommendation of the Government of India.

The neonates who received steroids in the age group of 28-31.6 weeks, there was statistically significant reduction in the risk of developing RDS, need for respiratory support, need for surfactant and need for inotrope. In the gestational age group age 32-33.6 weeks, there was no statistically significant reduction in the risk of developing RDS, need for respiratory support, need for surfactant and need for inotrope. The reduction in the above parameters is significant in the age group 28- 31.6 weeks as neonates equal to or more than 32 weeks have a better prognosis as compared to those below 32 weeks due to their relatively advanced gestational age and the associated better neonatal care and availability of surfactants in our NICU.

Elimian *et al.* [8] have assessed the effectiveness of incomplete course of antenatal steroids compared to placebo and found to be associated with reduction in the incidence of intraventricular hemorrhage, neonatal death in preterm. They observed increased mortality in the no steroid group (11.1%) compared to complete steroid group (0%), and the requirement of surfactant and RDS was higher in the no steroid group (68.2%) suggesting that antenatal steroid is a low-cost effective drug in the prevention of RDS even in a low-resource setting. The incidence and requirement of surfactant was low in the complete course of steroid group (3.1%) compared to the no steroid (20.8%) and partial cover steroid group (13.5%) suggesting cost benefit even with effect with partial coverage.

Adams TM *et al.* in the American Journal of Obstetrics and Gynaecology in 2015 states that the optimal therapeutic window for delivery after corticosteroid administration is 2-7 days, yet only 20-40% of women assessed at their institution for preterm labour delivered in that window [9].

In the Ohio Perinatal Quality Collaborative, 45% of women delivered in a 2-14 days window after receiving corticosteroid

[10].

Chien *et al*. presented data concerning antenatal steroid administration to 11440 infants in Canada. Only 30% of children completed the antenatal steroid course. Infants who received a complete steroid course exhibited a significant reduction in RDS risk when born before 24 weeks' or at 24-34 weeks' gestation. A partial steroid treatment course reduced the incidence of IVH (grades III and IV) and mortality among infants born at 24-35 weeks' gestation but had no significant effect on RDS. The incidence of NEC was similar in infants receiving a partial or complete course of steroids [11].

The efficacy of corticosteroids in the gestational age of less than 28 weeks could not be determined due a relatively small sample size of 8 participants in that gestational age group, hence an appropriate conclusion could not be drawn in our study in this gestational age group. There was a reduction in other parameters-however, it was not statistically significant. There is a reduction in the neonatal death amongst neonates of gestational age less than 32 weeks who received a complete course of antenatal corticosteroids. No statistically significant reduction in neonatal morbidity is seen amongst those who received optimum complete courses versus those who did not, explaining the need to immediately start the steroid course in a case of preterm labour to give benefit irrespective if the patient can complete the course before delivery. Referral doctors need to understand the same and give the first dose before transferring the patient, since time is of essence. The difference between the efficacy of the two drug forms could not be studied as there was significant difference between the proportion of use of both drugs (89 percent vs 11 percent) and would require a larger study and near equal number of cases for proving any benefits of one drug over another. There was no reduction in the incidence of necrotizing enterocolitis.

In our study no maternal complications or adverse events mentioned below were noted in any patient receiving ACS such as increase in the incidence of maternal infections, endometritis and chorioamnionitis, transient hyperglycemia (occurs 12 hours after the first dose and lasts for 5 days) or transient elevation of leucocyte count (elevation by 30% in 24 hours and lasts for about 3 days), pulmonary oedema in cases associated with combination treatment with tocolysis especially in cases with chorioamnionitis, fluid overload and multiple gestation and increase in uterine activity [12]. Short term neonatal adverse events of neonatal hypoglycaemia associated with ACS could not be assessed due to multiple confounding factors such as preterm birth, neonatal sepsis, diabetes mellitus in mother.

## Conclusion

The present study concluded that the antenatal corticosteroids have a coverage rate of 59.3% with Betamethasone as the most commonly used drug form. Maximum efficacy was noted in gestational age group 28-32 weeks with no complications.

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## Conflict of Interest

Not available

## Financial Support

Not available

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