

Original Research Article

Effect of antenatal corticosteroids on neonatal outcome in term elective caesarean section: a randomised controlled trial

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ABSTRACT

Background: Infants born at term by elective caesarean section are more likely to develop respiratory morbidity than infants born vaginally. Prophylactic corticosteroids in singleton preterm pregnancies accelerate lung maturation and reduce the incidence of respiratory complications. Thus, the aim of this randomized controlled trial was to assess the effect of antenatal corticosteroids on neonatal outcome among term pregnant women undergoing elective caesarean section.

Methods: It was an open labelled randomized controlled trial conducted among women with term pregnancy of 37-38+6 weeks and planned for caesarean section at term and who were willing to participate in the study. We randomized 50 pregnant women into intervention group which received antenatal corticosteroids in the form of injection dexamethasone 12 mg IM, 4 doses at 12 hourly intervals before term elective caesarean section and 50 pregnant women into control group which did not receive antenatal corticosteroid. Fetal outcomes were compared in both groups after caesarean section. Data were analysed using SPSS vs.20.

Results: Nearly half (54%) of pregnant women belonged age group of 21-25 years and majority (58%) of pregnant women belonged to 38-39 weeks of gestation. Out of 50 pregnant women in intervention group, only two percent neonates developed RDS, four percent neonates developed transient tachypnea of neonate (TTN) and six percent neonates required NICU admission which was lower than control group. However, difference between fetal outcomes in intervention and control group was not statistically significant ($p>0.05$).

Conclusions: Administration of prophylactic antenatal corticosteroids before 48 hours of elective term caesarean section does not have impact on fetal outcome in our study.

Keywords: Term pregnancy, Caesarean section, Antenatal corticosteroids, Fetal outcome, Randomized trial

INTRODUCTION

Prematurity represents a serious problem for healthcare services throughout the world. Of all the global births, 10% are preterm. Respiratory distress syndrome (RDS) continues to be the most important pulmonary problem during neonatal period, affecting large no. of premature infants.¹ Preterm birth can have significant short-term and

long-term effects. The short-term sequelae of preterm birth include respiratory distress syndrome, intraventricular haemorrhage (IVH), necrotizing enterocolitis (NEC), retinopathy of prematurity, patent ductus arteriosus and sepsis.²⁻⁴

Corticosteroids are given to women in early labour for the maturation of lungs more quickly and so they reduce mortality of babies due to breathing problems as

breathing problems are the main cause of death for babies born very early.⁵⁻¹⁵ This was shown by Liggins and Howie et al that if women were treated with antenatal corticosteroids, then infants of those women had fewer cases of respiratory distress syndrome than premature infants of women who were not given the corticosteroids.¹⁶

Uncertainty still exists around the use of antenatal corticosteroids at later gestations. This question has become increasingly important in view of increasing number of caesarean sections at both term and late preterm gestation.¹⁷ Caesarean section predisposes the neonate to respiratory complications including RDS and transient tachypnoea of the newborn.¹⁸⁻²⁰ This risk increases furthermore for the subgroup of children born after elective caesarean section, i.e. before onset of labour.²¹ Delaying the elective caesarean until 39 weeks or more appears to be an equally effective solution.²¹⁻²³ Subsequently more than 20 clinical trials conducted in high-and middle-income countries and a number of systematic reviews have confirmed the efficacy of antenatal corticosteroids in reducing the risk of RDS, neonatal death, IVH, NEC and early sepsis.^{12,24}

In Cochrane database systemic review 30 trials were done. Review shows that a single course of antenatal corticosteroids, given to the mother in preterm labor, helps in the maturation of lungs and reduces complications like intraventricular hemorrhage, RDS, hypoxic ischemic encephalopathy.²⁵

The structural and biochemical alterations induced by corticosteroids reduces the need for and duration of mechanical ventilation for newborns with respiratory insufficiency. This antenatal therapy should be considered not only because of the pulmonary maturation, but also for its protective role in the premature infant's brain.^{26,27}

Previous studies have shown, elective cesarean section to be associated with an increased risk of respiratory morbidity in neonates.²⁸⁻³⁵ It is plausible that hormonal and physiological changes associated with labour are necessary for lung maturation in neonates and that these changes do not occur in infants delivered by elective caesarean sections.³⁶⁻⁴⁰ During labour there is a rise in corticosteroid level which encourages the expression of the epithelial channel gene and allows the lung to switch from fluid secretion to fluid absorption. Elective caesarean section bypasses this mechanism, thereby predisposing to the increased risk of respiratory distress.⁴¹⁻⁴³

Recently, the American college of obstetricians and gynaecologists recommended antenatal corticosteroids for women at risk of late premature delivery greater than 34 weeks' gestation but not for women undergoing

planned caesarean at term; whereas according to the Royal college of obstetricians and gynaecologists antenatal corticosteroids should be given to all women with a planned elective caesarean section prior to 38 weeks' gestation.⁴⁵ It is currently recommended that planned caesarean delivery should be deferred to 39 weeks' gestation.^{46,47}

Hence this interventional study was carried out to assess the effect of antenatal corticosteroids on neonatal outcome among term pregnant women undergoing elective cesarian section.

METHODS

Study design and setting

It was an open labelled randomized controlled trial conducted in department of obstetrics and gynaecology, Vardhman Mahavir medical college and Safdarjung hospital, New Delhi during January 2018 to October 2018.

Sample size

We calculated sample size using formula for RCT for comparing between two means and taking observed difference in length of stay in neonatal intensive care unit as (Mean difference) -2.14 days with standard deviation of 3.44 days from previous study done by Alexandros et al and power as 80% and five percentages level of significance.⁴⁸

Formula for comparing mean of two groups:

$$N = \frac{2 \text{ (standard deviation)}^2 * (Z_{\alpha} + Z_{\beta})^2}{(\text{Mean difference})^2}$$

Where Z_{α} is value of Z at two-sided alpha error of 5% and Z_{β} is value of Z at power of 80% and mean difference is difference in mean values of two groups.

Sample size came out to be 41 patients in each study group. To reduce margin of error, total sample size taken was 100 (50 patients per group).

Study participants

Pregnant women with period of gestation between 37 weeks to 38 weeks and six days registered at dept. of obstetrics and gynaecology and planned for caesarean section at term were included in the study. Those women who in active labour, who have already received antenatal corticosteroids before 34 weeks of gestation and those pregnant women who had co-morbidities which could affect fetal outcome such as severe preeclampsia, intra-uterine growth retardation, oligo-hydramnios/ poly-hydramnios, medical diseases like GDM/ hypothyroidism/ heart diseases, antepartum haemorrhage

and preterm rupture of membranes excluded from the study.

Methodology

Women with term pregnancy 37-38+6 weeks who all were willing to participate in the study were enrolled for the study after taking written informed consent and explaining study procedure in local language. They were selected as per the inclusion and exclusion criteria. They were scheduled for the elective lower section CS. Women were categorized in to the intervention group and the control group randomly using sealed envelope. The intervention group received antenatal corticosteroids in the form of inj dexamethasone 12 mg IM, 4 doses at 12 hourly intervals before term elective caesarean section. The control group did not receive any antenatal corticosteroids. Both the groups were followed up as per the hospital protocols till the mother and the baby were discharged from the hospital. Maternal and fetal outcome parameters were recorded during this follow up period. APGAR score was calculated at one and five min of birth. The parameters calculated were heart rate, respiration, muscle tone, reflex irritability and colour of the baby. Maximum APGAR score is 10, normal is >7, low is <7.⁴⁹ Scoring of severity of respiratory distress syndrome is done on the basis of Downe's score in term infants. Score <4 no respiratory distress, 4-7 respiratory distress, >7 impending respiratory failure.⁵⁰ Neonates after birth were followed for transient TTN, oxygen saturation and neonatal sepsis. Maternal sepsis was diagnosed clinically in mother with fever >38 degree, chills, low abdominal pain, tachypnea, tachycardia, foul smelling vaginal discharge. It usually occurred after 24 hours and within 10 days of delivery.

Ethical issues

Study protocol was approved by institutional ethics committee of Vardhman Mahavir medical college and Safdarjung hospital, New Delhi. Written informed consent was taken from the participants after explaining the study procedure in local language. Confidentiality of data was maintained. Appropriate care was provided to neonates and mother who had any sort of complications post-delivery.

Statistical analysis

The data was entered in MS excel spreadsheet and analysis was done using statistical package for social sciences (SPSS) version 21.0. Categorical variables were presented in number and percentage (%) and continuous variables were presented as mean \pm SD and median. Normality of data was tested by Kolmogorov-Smirnov test. Quantitative variables were compared using unpaired t-test/Mann-Whitney test. Qualitative variables were compared using chi-square test / Fisher's exact test. A p value of <0.05 was considered statistically significant.

RESULTS

We studied 100 participants in this trial, 50 in each group. Nearly half (54%) of pregnant women belonged age group of 21-25 years and only 10% belonged to age group of >30 years. Majority (58%) of pregnant women belonged to 38-39 weeks of gestation. The frequency of elective caesarean section was slightly more that is 64% in POG 38-39 weeks than in POG 37-38 weeks. Intervention group and control group were comparable with respect to age and period of gestation ($p>0.05$) (Table 1).

Table 2 shows that among 50 neonates of control group, majority (96%) did not develop RDS and only 2 (4%) developed RDS and similarly, among 50 neonates of intervention group, most of them (98%) did not develop RDS and only one neonate developed RDS and difference between two groups was not significant ($p=0.557$). Thus, antenatal corticosteroids given before term elective caesarean section had no significant effect on prevention of RDS in neonates. TTN developed in 2 (4%) of neonates in intervention group and 4(8%) of neonates in control group but this difference was not significant ($p=0.399$). We found that among 50 intervention group neonates, only few (14%) needed oxygen and among 50 control group neonates, three fourth (74%) did not need oxygen and one fourth (26%) needed oxygen. However, this difference found to be non-significant ($p=0.134$). About three (6%) neonates in intervention group and six (12%) neonates in control group had low APGAR score but this difference was not significant ($p=0.487$). Our study showed that among intervention group, most of them (96%) neonates did not develop sepsis while only two (4%) developed sepsis and among control group, 49 (98%) did not develop sepsis while only one (2%) developed sepsis. Thus, p value comes out to be 0.557 which shows statistically insignificant result.

Table 2 shows that among 50 intervention group neonates, only three (6%) neonates needed NICU admission and among 50 control group neonates, six (12%) needed NICU admission and this difference was not significant ($p=0.487$). Out of 9 neonates who were admitted in NICU, nearly half (44%) neonates stayed for 1 day, one third (33%) neonates stayed for 2 days and around one fourth (22%) neonates stayed for 3 days in NICU.

In our study, there was no neonatal death reported in both the group and none of the neonate required mechanical ventilation in both the groups.

Table 3 shows that out of 50 mothers who received antenatal corticosteroids, most of them (90%) did not develop sepsis and 10% developed sepsis, whereas 92% mothers in control group did not develop sepsis and few mothers (8%) developed sepsis. However, this difference was insignificant ($p=0.725$).

Table 1: Baseline characteristics of intervention and control group.

Variables		Intervention group, (n=50), no. (%)	Control group, (n=50), no. (%)	Total, (n=100), no. (%)	P value
Age group in years	21-25	26 (52)	28 (56)	54 (54)	0.911
	26-30	19 (38)	17 (34)	36 (36)	
	>30	5 (10)	5 (10)	10 (10)	
Period of gestation (POG) in weeks	37-38	18 (36)	24 (48)	42 (42)	0.224
	38-39	32 (64)	26 (52)	58 (58)	

Table 2: Distribution of neonatal outcomes in intervention and control group.

Outcomes		Intervention group, (n=50), no. (%)	Control group, (n=50), no. (%)	Total, (n=100), no. (%)	P value
RDS#	No	49 (98)	48 (96)	97 (97)	0.557
	Yes	1 (2)	2 (4)	3 (3)	
TTN	No	48 (96)	46 (92)	94 (94)	0.399
	Yes	2 (4)	4 (8)	6 (6)	
Oxygen requirement	No	43 (86)	37 (74)	80 (80)	0.134
	Yes	7 (14)	13 (26)	20 (20)	
APGAR score	Normal	47 (94)	44 (88)	91 (91)	0.487*
	Low	3 (6)	6 (12)	9 (9)	
Neonatal sepsis	No	48 (96)	49 (98)	97 (97)	0.557
	Yes	2 (4)	1 (2)	3 (3)	
NICU admission	No	47 (94)	44 (88)	91 (91)	0.487*
	Yes	3 (6)	6 (12)	9 (9)	
NICU stay in days, (n=9)	1	2 (66.7)	2 (33.3)	4 (44.5)	0.472*
	2	1 (33.3)	2 (33.3)	3 (33.3)	
	3	0 (0)	2 (33.3)	2 (22.2)	

#RDS-respiratory distress syndrome, % TTN-Transient tachypnea of newborn, \$- NICU: Neonatal intensive care unit, *Fisher exact test.

Table 3: Distribution of maternal outcomes in intervention and control group.

Variables		Intervention group, (n=50), no. (%)	Control group, (n=50), no. (%)	Total, (n=100), no. (%)	P value
Maternal sepsis	No	45 (90)	46 (92)	91 (91)	0.725*
	Yes	5 (10)	4 (8)	9 (9)	

*Fisher exact test

DISCUSSION

Prematurity represents a serious problem for healthcare services throughout the world. RDS continues to be the most important pulmonary problem during the neonatal period, affecting a large number of premature infants. Caesarean section is a risk factor for the development of neonatal respiratory complications, mostly RDS and TTN, both in term and preterm infants.¹⁰ Infants born at term by caesarean delivery are more likely to develop respiratory morbidity than infants born vaginally, and this risk increases furthermore for the subgroup of children born after elective caesarean section, i.e., before onset of labour.

To prevent RDS and TTN, according to the Royal college of obstetricians and gynaecologists' antenatal corticosteroids should be given to all women with a planned elective caesarean section prior to 38+6 weeks' gestation.⁴⁵ In our study we found that giving antenatal

corticosteroids before term elective caesarean section at 37 weeks to 38+6 weeks had statistically significant effect on neonatal outcome.

The present study was an interventional study in which the women with 37-38+6 weeks of gestational age were enrolled for the study and scheduled for elective LSCS. They were randomized into intervention and control group and intervention group was given antenatal corticosteroids.

Development of RDS in neonates

Out of 50 neonates in the intervention group, majority (98%) of neonates did not develop RDS and only one (2%) developed RDS. Whereas, 48(96%) neonates in control group did not develop RDS and two (4%) neonates developed RDS. In our study the effect of antenatal corticosteroids on RDS was not statistically significant. Sotiriadis et al have done the similar study of

comparing effect of prophylactic antenatal corticosteroid administration (betamethasone or dexamethasone) on neonatal outcome given before elective caesarean section at term (at or after 37 weeks of gestation).⁵¹ They did not find statistically significant reduction in the incidence of neonatal RDS (RR 0.32; 95% CI 0.07 to 1.58).⁵⁷ Similar findings were reported by Stutchfield et al in their study.⁵²

TTN as neonatal outcome

In our study TTN was developed in two (4%) neonates in intervention group and four (8%) of neonates in control group. While 48 (96%) neonates in intervention group did not develop TTN and 46 (94%) neonates in control group did not develop TTN and P value came out to be 0.678 which showed statistically insignificant results. Similarly, Saccone et al have shown in their study that infants delivered by planned caesarean delivery at ≥ 37 weeks' gestation whose mother received prophylactic antenatal corticosteroids 48 hours before delivery had lower risk of transient tachypnea of the newborn (RR: 0.38, 95% CI 0.25 to 0.57).⁵³ The results were significant in their study. Madar et al and Barber et al also reported similar results in their study.^{54,55}

Oxygen needs to neonates

In this study, out of 50 neonates in intervention group, majority (86%) neonates did not need oxygen and only (14%) neonates needed oxygen. Whereas, in control group, around three fourth (74%) neonates did not need oxygen and one fourth (26%) neonates needed oxygen. This result was also insignificant. Similar study done by Saccone et al showed that neonates delivered by planned caesarean delivery at ≥ 37 weeks' gestation after receiving prophylactic antenatal corticosteroids 48 hours before delivery had significantly less need of oxygen (mean difference -2.06 hours, 95% confidence interval -2.17 to -1.95) and lower percentage of maximum inspired oxygen concentration (-0.66%, -0.69% to -0.63%).⁵³ Thus the results are not conclusive for the administration of antenatal corticosteroids before term elective caesarean section.

APGAR score in neonates

Our study showed that 47 (94%) neonates in intervention group and 44 (88%) neonates in control group had normal APGAR score. About three (6%) neonates in intervention group and six (12%) neonates in control group had low APGAR score. Similarly, Jain et al assessed the effect of prophylactic corticosteroid administration before elective caesarean section at term and showed that APGAR score was higher in these neonates as compared to those who had no exposure to prophylactic corticosteroid.⁵⁶ Stutchfield et al and Barber et al reported the similar results in their studies.^{52,55} This inconsistency in result may be due to difference in

sample size and study setting of our study and other study.

NICU admission rate in neonates

In our study, majority of (94%) neonates in intervention group did not require NICU admission and only three (6%) neonates needed NICU admission. Whereas in control group, majority (88%) neonates did not require NICU admission and six (12%) needed NICU admission and this difference was insignificant. Similarly, Barber et al found in their study that when women were given two intramuscular injections of 12 mg of betamethasone, two doses for 48 hours, the rate of admission was 5.2% at 37 weeks, 2.8% at 38 weeks, and 0.6% at 39 weeks which was much less than the infants born to mother in control group.⁵⁵ But the results were insignificant as our study. This was also supported by studies done by Madar et al, Jain et al and Saccone et al in their study.^{53,54,56}

Length of NICU stay

In the present study, 66% neonates in intervention group and 33% neonates in control group stayed for one day in NICU, one third (33%) neonates in both the groups stayed for two days in NICU and about 33% neonates in control group admitted for three days in NICU. Sotiriadis et al have shown that giving prophylactic antenatal corticosteroid before elective caesarean section at term in 467 pregnant women, difference in length of stay in neonatal intensive care unit was (MD) -2.14 days; 95% CI -5.58 to 1.30).⁵¹ The results were significant in this study as large sample size was taken in this study. Madar J et al have shown the similar results in their study.⁵⁴

Need of mechanical ventilation

Our study showed that none of neonates in either control or intervention group had need of mechanical ventilation. Study done by Sotiriadis et al have shown that giving prophylactic antenatal corticosteroid before elective caesarean section at term had need for mechanical ventilation (RR 4.07; 95% CI 0.46 to 36.27).⁵¹ The results were statistically insignificant. Similar results were shown by Stutchfield et al, Saccone et al and Barber et al.^{52,53,55}

Maternal outcome

Our study shows that among intervention group 45 (90%) mothers receiving antenatal corticosteroids did not develop sepsis and 5 (10%) mothers developed sepsis while 46 (92%) mothers in control group did not develop sepsis and 4 (8%) developed sepsis which shows statistically insignificant results. Review done by Roberts et al included twenty-one studies and enrolled 3885 women and 4269 infants and showed that antenatal corticosteroids does not increase the risk of maternal sepsis or chorioamnionitis.¹² Study done by Vaisbuch et al in which he included 105 women and noticed that total

leucocyte count increases transiently after administration of corticosteroids that falls after one day.⁵⁷ This difference in findings may be due to difference in sample size and study setting.

CONCLUSIONS

In this randomized controlled trial, we found that incidence of RDS, TTN, NICU admission and oxygen need among neonates in intervention group was lower than that of control group. Thus, Administration of prophylactic antenatal corticosteroids before 48 hours of elective term (37wks to 38+6wks) caesarean section does not have impact on fetal outcome in our study. A large multicentric study is warranted to validate our study findings.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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