

RESULTS

A total of 286 women fulfilled the inclusion criteria for the study. 143 were randomized to receive dexamethasone (cases) and 143 were randomized to receive placebo (controls). Of these, 34 women were discharged from the hospital during pregnancy and were lost to follow-up, 13 among the cases and 21 among the controls, therefore 130 women remained in the dexamethasone group and 122 in the placebo group with 11.9 % of losses after randomization.

Table 1 shows the socio demographic characteristics of the participants. The mean maternal age of the cases is 31.2 ± 4.8 years while that of the controls is 30.1 ± 4.9 years. These two mean maternal ages showed no statistically significant difference ($p= 0.55$). With respect to occupation, there was no significant difference between the cases and the controls ($p=0.35$). There were no significant differences noted also in the religious beliefs, tribe, and highest level of education of the participants.

Table 1: Sociodemographic Characteristics of the Cases and Controls

Variables	Cases N=130	Control N=122	χ ² (p-value)
Maternal age (mean ±SD)	31.2 ±4.8	30.1±4.9	0.55
Occupation			
Skilled	83(52.9)	74(47.1)	1.181(0.55)
Semi-skilled	30(46.2)	35(53.8)	
Unskilled	17(56.7)	13(43.3)	
Highest level of education			
Primary and below	5(41.7)	7(58.3)	2.105(0.35)
Secondary	33(45.8)	39(54.2)	
Tertiary	92(54.8)	76(45.2)	
Tribe			
Hausa	14(45.2)	17(54.8)	(2.729)0.44
Igbo	47(53.4)	41(46.6)	
Yoruba	55(55.6)	44(44.4)	
Others	14(41.2)	20(58.8)	
Religious belief			
Christianity	76(49.4)	78(50.6)	(1.609)0.44
Islam	53(54.6)	44(45.4)	
Traditional	1(100.0)	0(0.0)	

Table 2 shows the obstetric characteristics of the participants, 59.5% of the cases were booked while 40.5% of the controls were booked and this difference was statistically significant ($p=0.02$). There was no statistically significant difference in the parity, birth weight of the fetus and gestational age at delivery of the cases compared to the controls.

Table 2: Obstetric Characteristics of the Cases and Controls

Variable	Cases N=130	Control N=122	P value
Booking status			
Booked	69(59.5)	47(40.5)	0.02
Unbooked	61(44.9)	75(55.1)	
Parity	1(0,2)*	1(0,2)*	0.55
Birth weight in grammes	2974.61(±453.29)	2945.90(±561.15)	0.65
GA at Delivery	35.68(±0.93)	35.75(±0.94)	0.51

*Median(inter quartile range)

Table 3 shows the Incidence of respiratory morbidity among the cases and controls. Any neonate who had any of the 3 primary outcome measures vis respiratory distress syndrome, transient tachypnea of the newborn or need for ventilatory support is said to have had a respiratory morbidity. The risk for the occurrence of at least one type of respiratory morbidity was significantly lower in those that received corticosteroid compared to those that did not receive. (OR= 0.12, 95% C.I =0.04 – 0.31, P=0.00003). Corticosteroid administration was associated with significant reduction in the rate of respiratory distress syndrome (O.R=0.27, 95% C.I=0.08 – 0.84, p=0.032), Transient tachypnea of the newborn(O.R=0.11, 95% C.I=0.02 – 0.49, p=0.0016), and need for ventilatory support (O.R=0.15, 95% C.I=0.05 – 0.39, p=0.00006).

Table 3: Incidence of Respiratory morbidity among cases and controls

Variables	Cases N=130	Control N=122	Odds ratio	95% C.I	p-value
Respiratory Morbidity					
Yes	5(3.8)	31(25.4)	0.12	0.04 – 0.31	0.000003*
No	125(96.2)	91(74.6)	Ref	Ref	
Respiratory distress syndrome					
Yes	3(3.1)	13(10.7)	0.20	0.06 - 0.69	0.032*
No	127(96.9)	109(89.3)	Ref	Ref	
Transient tachypnea of newborn					
Yes	2(1.5)	15(12.3)	0.11	0.02 – 0.49	0.0016*
No	128(98.5)	107(87.7)	Ref	Ref	
Need for ventilatory support					
Yes	5(3.8)	26(21.3)	0.15	0.05 - 0.39	0.00006*
No	125(96.2)	96(78.7)	Ref	Ref	

*Significant p-value

Table 4 shows the association of other non-respiratory neonatal complications with dexamethasone use. Corticosteroid administration did not significantly affect the risk of hypoglycaemia, neonatal sepsis, neonatal jaundice, neonatal death and feeding difficulties. Corticosteroid use however significantly reduced the risk of birth asphyxia (O.R = 0.25, 95% C.I = 1.57 – 10.47, p= 0.004), admission to neonatal intensive care unit (O.R= 0.41, 95% C.I= 0.21 – 0.78, p=0.009) and need for active resuscitation at birth(O.R =0.31, C.I= 0.12 – 0.76, p=0.014).

Table 4: Bivariate analysis of other neonatal complications among cases and controls

Variables	Cases N=130	Controls N=122	Odds ratio	95% C.I	p-value
Birth Asphyxia					
Yes	6(4.6)	20(16.4)	0.25	0.10 – 0.63	0.004*
No	124(95.4)	102(83.6)	Ref	Ref	
NICU admission					
Yes	17(13.1)	33(27.0)	0.41	0.21 - 0.78	0.009*
No	113(86.9)	89(73.0)	Ref	Ref	
Hypoglycemia					
Yes	10(7.7)	10(8.2)	0.93	0.38 – 2.28	0.93
No	120(92.3)	112(91.8)	Ref	Ref	
Neonatal sepsis					
Yes	10(7.7)	11(9.0)	0.84	0.35 – 2.02	0.88
No	120(92.3)	111(91.0)	Ref	Ref	
Neonatal jaundice					
Yes	9(6.9)	10(8.2)	0.83	0.33 – 2.08	0.89
No	121(93.1)	112(91.8)	Ref	Ref	
Neonatal death					
Yes	2(1.5)	4(3.3)	0.46	0.10 - 2.21	0.62
No	128(98.5)	118(96.7)	Ref	Ref	

Need for resuscitation at birth					
Yes	7(5.4)	19(15.6)	0.31	0.13 – 0.75	0.014
No	123(94.6)	103(8.4)	Ref	Ref	
Feeding difficulties					
Yes	1(0.8)	3(2.5)	0.31	0.04– 2.22	0.58
No	129(99.2)	119(97.5)			

Table 5 shows the association between maternal factors and the occurrence of respiratory morbidity in the neonate. The presence of hypertension, preterm labour, pre labour rupture of membranes and antepartum haemorrhage had no significant effect on respiratory morbidity.

Delivery by caesarean section compared to vaginal delivery (O.R= 2.11, 95% C.I of 1.01 – 4.44, p=0.04) and presence of diabetes mellitus (O.R=4.12, 95% C.I= 1.59 – 10.71, p=0.0054) significantly increased the risk of respiratory morbidity.

Table 5: Bivariate association between maternal factors and effect on respiratory morbidity

Variable	Respiratory morbidity		Odds Ratio	95% C.I	P value
	Yes (n=36)	No (216)			
Route of delivery	Yes	No			
Caesarean section	24(18.6)	105(81.4)	2.11	1.01 – 4.43	0.04
Vagina delivery	12(9.8)	111(90.2)	Ref		
Hypertension					
Yes	13(15.3)	72(84.7)	1.13	0.54 – 2.36	0.89
No	23(13.8)	144(86.2)	Ref		
Diabetes Mellitus					
Yes	8(36.4)	14(63.6)	4.12	1.59 – 10.71	0.0054
No	28(12.2)	202(87.8)	Ref		
Preterm Labour					
Yes	2(5.3)	36(94.7)	0.29	0.07 – 1.26	0.14
No	34(15.9)	180(84.1)	Ref		
Pre-labour rupture of membranes					
Yes	2(4.9)	39(95.1)	0.27	0.06 – 1.14	0.10
No	34(16.1)	177(85.1)	Ref		
Ante partum haemorrhage					
Yes	6(11.8)	45(88.2)	0.76	0.30 – 1.92	0.72
No	30(14.9)	171(85.1)	Ref		

Table 6 shows the multiple logistic regression analysis of factors which had significant effects on respiratory morbidity. After correcting for presence of diabetes mellitus and delivery by caesarean section, corticosteroid administration to the mother at risk of late preterm delivery reduced the risk of respiratory morbidity almost 9-fold (AOR= 0.11, 95% C.I= 0.04 – 0.31, $p < 0.00001$)

Table 6: Multiple logistic regression analysis of Corticosteroid administration as an independent determinant of Respiratory morbidity

Variable	AOR	95% C.I	p value
Corticosteroid administered	0.11	0.04 – 0.31	0.0000
Diabetes mellitus	4.46	1.50 - 13.29	0.0071
Ceasarean section	2.12	0.96- 2.16	0.0626

AOR= Adjusted odds ratio