A clinical trial of Surfactant on 100 Respiratory Distress Syndrome(RDS) in 100 preterm and late preterm neonates admitted in pediatric department during the period January 2018-June 2019 ; An Observational study

R.Sujatha Devi[1], Satya kumari[2], Indira[3]

[1]Department of Pediatrics, AMC, Visakhapatnam.

[2]Department of Pediatrics, Andhra Medical College,Visakhapatnam,Andhrapradesh. [3]Department of Pediatrics, ACMR.Government Medical college, Nellore, Andhrapradesh

ABS TRACT

BACKGROUND

RDS Respiratory Distress is a common condition in preterm and late preterm neonates whose age less than 1.5kgs need some intervention like intubation administration of surfactant1,2 will prove that early extubation and better outcome is possible.

AIM

A clinical trial including intervention and observation of 100 preterm neonates with RDS admitted in pediatric ward.

RESULTS

Out of 100 neonates, most of the neonates 34 (66.6%) in the surfactant group and 37 (75.0%) neonates in the control group were between 30wks to 32wks of GA respectively. 12 (25.0%) in the surfactant group and 10(19.4%) in the control group were between.27wks to 29wks of GA respectively. very less 4 (8.3%) in the study group and 3 (5.5 %) in the control group were between 32wks of GA to 35 wks respectively.

CONCLUSIONS

The study concludes that among spontaneously5 breathing premature infants treated with INSURE, decreased the need for subsequent MV by 22%. The higher birth weight, the use of antenatal steroids16,17 the lower RDS score at the time of procedure and the early use of surfactant are the good predictors in the INSURE success group.

KEYWORDS

RDS, Preterm, Intubation, Surfactant(INSURE), GA (Gestational age), MV (Mechanical ventilation),Pulmonary Hemorrhage,CPAP.

Corresponding Author:
Dr.R.Sujatha Devi , M.D Assistant professor of Pediatrics, AMC, Visakhapatnam.
E-mail: sujatha12341234@gmail.com

How to Cite This Article:
Sujatha Devi, Satya kumara, Indira. A clinical trial of Surfactant on 100 Respiratory Distress Syndrome(RDS) in 100 preterm and late preterm neonates admitted in pediatric department during the period January 2018-June 2019 ; An Observational study.. J Evid Based Med Healthc 2022;9(01):1-7.

Submission 16-12-2021,
Peer Review 23-12-2021,
Acceptance 30-12-2021,
Published 06-01-2022.

MATERIALS AND METHODS

Newborn babies with RDS to NICU, Department of Pediatric, King George Hospital, Andhra Medical College, and Visakhapatnam.

A total of 100 neonates who came with respiratory distress syndrome with <35 wks and <1.5kg were taken in the study including both the sex. The study was conducted for 18 months.

All babies, both inborn & out born, admitted to NICU with gestational age <35wks and <1.5kgs with RDS by clinical (Silverman - Anderson scoring) and radiographic criteria and requiring supplemental oxygen by NCPAP, or by oxygen hood were taken .RDS was defined as clinical respiratory distress in the presence of chest X-ray evidence of lung field granularity, small lung volumes and air bronchogram.

OBSERVATION AND ANALYSIS

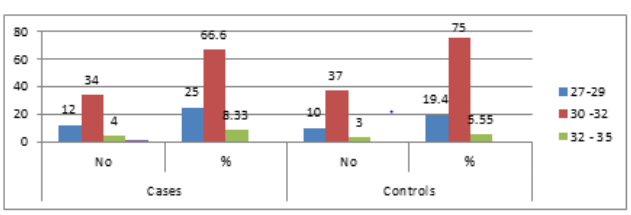
A total of 100 infants were included in the study. Of these (50 surfactant, 50 control) were taken. The study groups were similar with regard to baseline characteristics .

	Cases		Controls	
Gestational age	No	%	No	%
27-29	12	25	10	19.4
30 -32	34	66.6	37	75
32 - 35	4	8.33	3	5.55
Total	50	100	50	100
	Mean±SD =30.36±1.96		Mean±SD =30.56±1.73	

Table 1: Gestational Age In Two Groups Studied

P = 0.65 (Not significant)

In two groups most of the babies are 30-32 weeks gestational age 66.6% and 75% in study and control groups respectively.

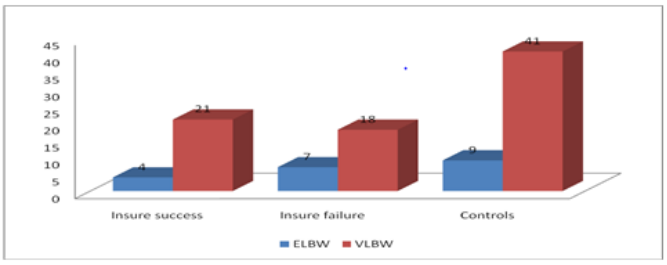


Fig;1;Gestational Age In Two Groups

	Cases				Controls	
	Insure success		Insure failure			
	No	%	No	%	No	%
ELBW	4	16.6	7	27.7	9	16.7
VLBW	21	83.3	18	72.2	41	83.3
	Mean±SD = 1.30±0.20		Mean±SD = 1.19±0.20		Mean±SD=1.22±0.17	
	P = 0.01*					
					P = 0.59	

Table-2: ELBW/VLBW In Two Groups Studied

ELBW/VLBW in two groups studied



The mean weight in the Insure success and the failure group were 1.30 ± 0.20 & 1.19 ± 0.20 respectively with P=0.01 is statistically significant. The control group does not show any significant difference with the mean weight being 1.22 ± 0.17. More the birth weight better is the INSURE outcome.

	Cases		Controls	
Gender	No	%	No	%
Female	15	30.6	20	38.9
Male	35	69.4	30	61.1
Total	50	100	50	100

Table 3; Gender Distribution Of Patients Studied

P=0.458

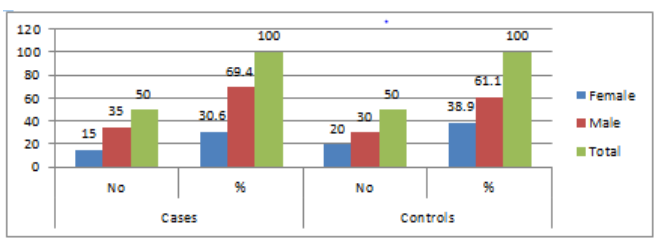


Fig 4; Gender Distribution

In our study Males constituted more both in study group and control group. 35(69.4%) in surfactant group and 30 (61.1%) in control group were males.

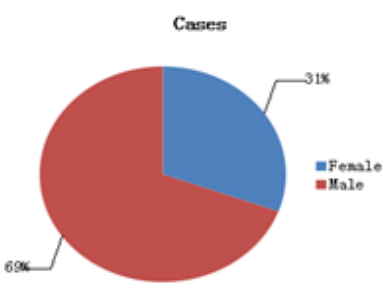


Fig-5 : Pie Chart Showing Gender Distribution Of Patients Studied

The place of delivery did not show any statistical difference between the study group and the control group. Almost 25 (50%) in the study group and 21 (41.7%) in the control group are delivered in our hospital. 25(50%) in study group and 29 (58.3%) in control group were extramural like PHC, home delivery or private hospital delivery.

Mode of delivery	Cases		Controls	
	No	%	No	%
NVD	16	30.6	19	38.9
LSCS	34	69.4	31	61.1
Total	50	100	50	100

Table 4 : Mode Of Delivery In Two Groups Studied

P=0.458 , not significant, chi-square test

Whatever the mode of delivery the outcome in study and control groups
Shows no significant difference.

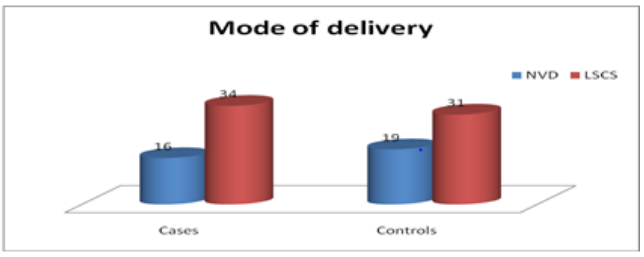


Fig 6 : Mode Of Delivery In Two Groups Studied

Antenatal Steroids	Cases		Control group (50) (%)
	Insure success (25)(%)	Insure failure (25)(%)	
0	3 (11.1)	12 (50)	28 (55.5)
1	11 (44.4)	7 (27.7)	15 (30.5)
2	11 (44.4)	6 (22.2)	7 (13.8)
	P = 0.02*		P=0.032*

Table 5: Antenatal Steroids In Two Groups

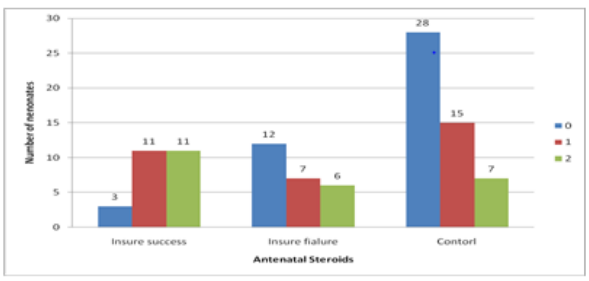


Fig 7 ; Bar Graph Showing Antenatal Steroids In Two groups

score	Cases				Controls (50)	
	Insure success (25)		Insure failure(25)			
	No.	%	No.	%	No	%
01-Mar	6	22.2	3	11.1	0	0
04-Jun	18	72.2	16	66.6	38	75
07-Oct	1	5.55	6	22.2	12	25
	Mean ± SD =4.50±1.1		Mean ± SD = 5.44±1.1			
	Mean ± SD = 5.63±1.19				Mean ± SD = 6.57±1.34	
Total	P= 0.009**				P = 0.006**	

Table 6: Silverman – Anderson Score In Two Groups

P is significant, Fischer Exact test(1-3 mild,4-6 moderate,7-10 severe)

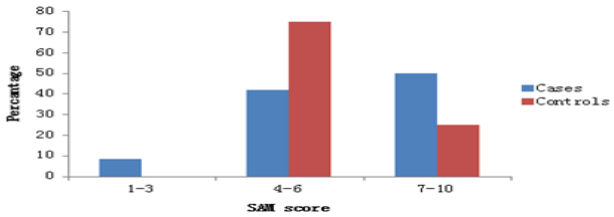


Fig 8 : Bar Graph Showing Silverman – Anderson Score In Two Groups

All the neonates (cases & control group) needed CPAP7 at the time of admission. The cases received surfactant, in which 47(94.4%) & 3(5.6%) received one and two doses6 respectively. out of 50 neonates 25 (50%) of neonates needed MV in study group while 36 (72.3%) in control group required MV which is statistically significant6. The duration of MV is more in the control group then the surfactant group. 30 (61.1%) in the control group required MV even after 4 days whereas 2(2.77%) in the surfactant group is on ventilator which is statistically significant.

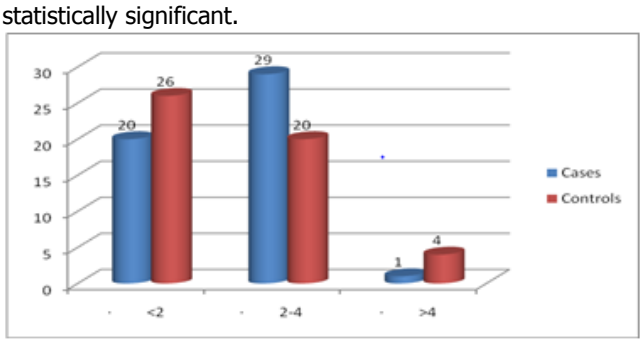


Fig 9 : Bar Graph Showing Number Of Days On CPAP

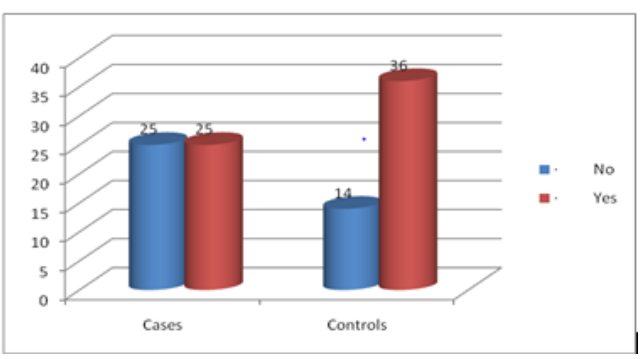


Fig 10 : Bar Graph Showing Whether Baby Needed MV

Need for MV	CASES		CONTROL	
	No	%	No	%
YES	25	50	36	72.2
NO	25	5 0.0	14	27.7
Total	50	100	50	100

Table -7: Subsequent Ventilation

P=0.053+, Significant , Chi-Square test

The primary outcome in the study group is the need for the subsequent ventilation. 25 (50%) in the surfactant group required MV & 36 (72.3%) in the control group required MV. The use of surfactant decreased the need for MV by 22% in study group9,12 than control group. 21 (41.7%) in the surfactant group & 27 (55.5%) in the control group showed mortality.

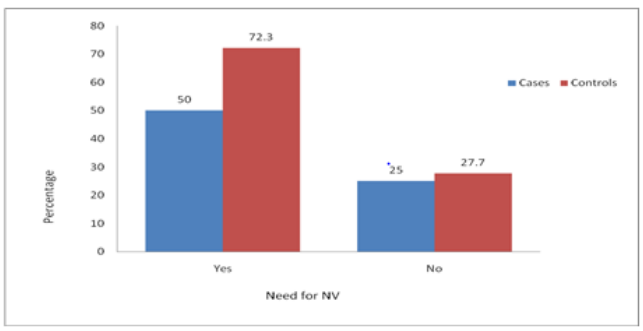


Fig- 11 : Bar Graph Showing Subsequent Ventilation

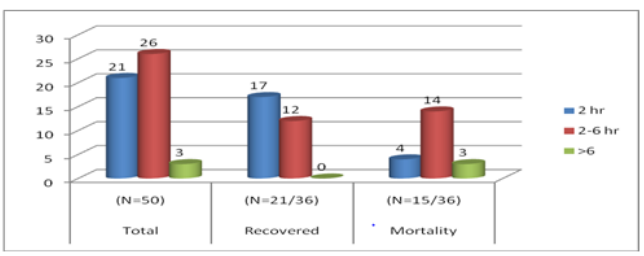


Fig-12 : Bar Graph Showing Number Of Hrs Insure Performed(Surfactant Group)

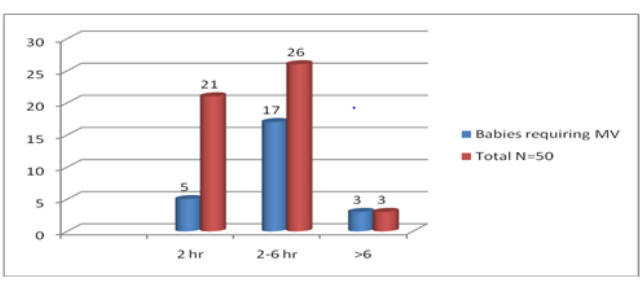


Fig-13 : Bar Graph Showing Number Of Hrs Insure Performed(Control Group)

	Surfactant group		Control group	
	Pre surfactant	Postsurfactant	Pre ventilation	Post ventilation
a/A ratio (Mean ±SD)	0..21± 0.06	0.33± 0.09	0.25± 0.08	0.23±0.09
	P = 0.0001 ***		P = 0.34	

Table-7. Effectiveness Of Intervention On Oxygenation

The mean value of the a/A ratio in the surfactant group were 0.21±0.06 in pre surfactant group and 0.33±0.09 in post surfactant group.(p = 0.0001**).In the control group the ratio is 0.25± 0.08 in Pre ventilation group and 0.23±0.09 in post ventilation group. There is a significant increase in the oxygenation in the surfactant group compared to control group after the intervention

	Early surfactant (<2/2hrs) Mean±SD	Late surfactant (> 2hrs) Mean±SD
Pre surfactant a/A ratio	0.25±0.05	0.18±0.06
Post surfactant a/A ratio	0.38±0.08	0.30± 0.08
P value	0.003*	0.007*

Table-8: Surfactant Oxygenation In Early Vs Late Administration

The mean post surfactant a/A ratio in the early surfactant is 0.38±0.08 & late surfactant is 0.30±0.08 which is significant.

CONCLUSION

1. This study concludes that among spontaneously breathing premature infants treated with INSURE, decreased the need for subsequent MV by 22%5 .
2. The higher birth weight, the use of antenatal steroids, the lower RDS score at the time of procedure and the early use of surfactant as the good predictors in the INSuRE success group.
3. There is a significant decrease in the need for MV in the surfactant group compared to control group.
4. The reduction in the need for MV decreased the risk of air leak syndrome and is advantageous in medical settings where resources are limited like in our country.
5. The shorter requirement of respiratory support contributes to the decreasing stay in the intensive care unit which can be attributed as a cost effective treatment.

REFERENCES

[1] Halliday HL. Recent clinical trials of surfactant treatment for neonates. Biol Neonate. 2006;89:323–329.
[2] Enhorning G, Shennan A, Possmayer F. Prevention of neonatal respiratory distress syndrome by tracheal instillation of surfactant: a randomised clinical trial. Paediatrics. 1985;76:145–153.
[3] Kendig JW, Notter RH, Cox C. Surfactant replacement therapy at birth: final analysis of a clinical trial and comparisons with similar trials. Paediatrics. 1988;82:756–762.
[4] Merritt TA, Hallman M, Bloom BT. Prophylactic treatment of very premature infants with human surfactant. N Engl J Med. 1986;315:785–790.
[5] Gopel W, Kribs A, Ziegler A, et al. Avoidance of mechanical ventilation by surfactant treatment of spontaneously breathing preterm infants (AMV): an open-label, randomised, controlled trial. Lancet. 2011;378:1627–34.
[6] Soll R, Ozek E. Multiple versus single doses of exogenous surfactant for the prevention or treatment of neonatal respiratory distress syndrome. Cochrane Database Syst Rev. 2009. p. CD000141.
[7] Dani C, Bertini G, Pezzati M, et al. Early extubation and nasal continuous positive airway pressure after surfactant treatment for respiratory distress syndrome among preterm infants <30 weeks' gestation. Pediatrics. 2004;113:560–3.
[8] Bohlin K, Gudmundsdottir T, Katz-Salamon M, et al. Implementation of surfactant treatment during continuous positive airway pressure. J Perinatol. 2007;27:422–7.
[9] Stevens TP, Harrington EW, Blennow M, et al. Early

surfactant administration with brief ventilation versus selective surfactant and continued mechanical ventilation for preterm infants with or at risk for respiratory distress syndrome. Cochrane Database Syst Rev . 2008;CD003063.

[10] Sandri F, Plavka R, Ancora G, et al. Prophylactic or early selective surfactant combined with nCPAP in very preterm infants. Pediatrics. 2010;6:1402–9.

[11] Rojas-Reyes MX, Morley CJ, Soll R. Prophylactic versus selective use of surfactant in preventing morbidity and mortality in preterm infants. Cochrane Database Syst Rev. 2012;3:CD000510.

[12] Aldana-Aguirre JC, Pinto M, Featherstone RM, et al. Less invasive surfactant administration versus intubation for surfactant delivery in preterm infants with respiratory distress syndrome : a systematic review and meta analysis. Arch Dis Child Fetal Neonatal Ed. 2017;102:F17–F23.

[13] Oncel MY, Arayici S, Uras N, et al. Nasal continuous positive airway pressure versus nasal intermittent positive-pressure ventilation within the minimally invasive surfactant therapy approach inpreterm infants: a randomised controlled trial. Arch Dis Child Fetal Neonatal Ed. 2016;101:f323–f328.

[14] Jobe AH, Mitchell BR, Gunkel JH. Beneficial effects of the combined use of prenatal corticosteroids and postnatal surfactant on preterm infants. Am J Obstet Gyneco11993; 168: 508-513

[15] White A, Marcucci G, Andrews E, et al. Antenatal steroids and neonatal outcomes in controlled clinical trials of surfactant replacement. Am J Obstet Gyneco11995; 173: 286-290

[16] Schmölzer GM, Kumar M, Pichler G, et al. Non-invasive versus invasive respiratory support in preterm infants at birth: systematic review and meta-analysis.

[17] Pfister RH, Soll RF. Initial respiratory support of preterm infants: the role of CPAP, the INSURE method, and noninvasive ventilation. Clin Perinatol. 2012;39(3):459-481.

[18] Thin catheter surfactant administration during spontaneous breathing in very low birth weight infants is associated with reduced need for mechanical ventilation. Benjamin J, Wright CJ.J Pediatr. 2013 Sep;163(3):923-4.