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CLINICAL UTILITY OF CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) IN RESPIRATORY DISTRESS SYNDROME (RDS) BABIES AND THEIR COMPLICATIONS.

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ABSTRACT

Background: Respiratory distress syndrome (RDS) historically called hyaline membrane disease is mainly a developmental disorder of preterm neonates due to structural immaturity of the lungs and surfactant deficiency. The incidence of RDS is inversely proportional to gestational age and birth weight. Despite recent advancements, RDS is still the most common cause of morbidity and mortality in the newborn group.
Methods: It was a descriptive longitudinal observational study including all preterm neonates with 30-37 weeks' gestational age and grade 1 & 2 RDS and was conducted over 2 years' duration at a tertiary level setup.
Results: 97 neonates managed only with CPAP, all had good outcome. Out of 19 neonates managed by CPAP+ surfactant,18(94.7%) had good outcome. Out of 6 neonates managed by CPAP+ Surfactant+ Mechanical ventilation, 2(33.3%) had good outcome and 8 neonates were managed by CPAP+MV of which 4(50%) had good outcome. 43.8%(57) preterm RDS neonates were given early CPAP and 56.2% (73) were given late CPAP. The success rate in case of early CPAP was 54 (94.7%), whereas in case of late CPAP, it was only 62(84.9%) out of 73. In early CPAP, 3 patients (5.3%) required surfactant and ventilation whereas in late CPAP 22 patients (30.1%) required surfactant and 11 (15.1%) required ventilation. Overall mortality in early CPAP was 3.5% whereas in late CPAP it was 9.6%. Only 1.7%(2) developed pneumothorax in CPAP success and 28.6%(4) developed pneumothorax among CPAP Failure cases.
Conclusion: Antenatal steroids not only play a role in reducing the severity of RDS but also in their good outcome. Early CPAP in

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comparison to late CPAP has a maximum survival rate, minimum mortality rate, less requirement of surfactant and ventilation support and CPAP success rate was high. Nasal trauma due to CPAP was directly related to the duration of CPAP application.

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INTRODUCTION:

Respiratory distress syndrome (RDS) historically called hyaline membrane disease (HMD) is a developmental disorder of mainly preterm infant due to structural immaturity of the lungs and surfactant deficiency. [1]

RDS is defined as respiratory distress of early-onset appearing within 6 hours of birth in a premature baby with

- RR>60/min
- Intercostal retractions
- Expiratory grunting
- +/- Cyanosis. [1]

Surfactant dipalmitoyl lecithin cox phosphatidylcholine is synthesized by type 2 alveolar cells which lower the surface tension & prevents alveolar collapse, and increases with progression of gestational age with protective nature against the occurrence of HMD.

The incidence of RDS is inversely proportional to gestational age and birth weight [2]. Despite of the recent advancements, RDS is still the most common cause of mortality and morbidity in newborn age group [3]. According to NNPD [4] data involving 151436 intramural deliveries in 2002-2003 incidence of preterm delivery is 14.5% with incidence of RDS in preterm babies being 1.2%, and it was the primary cause of mortality in 13.5%. According to NICHD [5] 2007, the total incidence of preterm in our population is 9%, with the occurrence of RDS in preterm being 44%.

In 1960s mechanical IPPV became widely accepted as the standard treatment of RDS in the newborn but mortality was still high in infants less than 1500gms or babies requiring ventilation on first day of life [6, 7, 8].

Although surfactant replacement thereby is an ideal treatment for RDS, it is not cost effective which makes it difficult to implement on case to case basis. Therefore, another method for improving oxygenation in an infant with RDS was looked for, and in 1971 Gregory et al. used Continuous Positive Airway Pressure in the treatment of RDS [9]. Infants with RDS presents with reduced lung compliance, and collapsed alveoli due to increased surface tension during expiration. The administration of oxygen with the help of CPAP will prevent alveoli from collapsing and ensure optimum gas exchange throughout the respiratory cycle. Also, the advent of less invasive CPAP has allowed for early treatment of RDS in neonates to intervene as early as possible and to avoid invasive procedures such as intubation, ultimately reducing mucociliary flow, prevent secondary infection and minimize volume trauma to the respiratory circuit.

Bubble CPAP is a newer CPAP delivering system with underwater seal. Various types of bubble CPAP includes blender CPAP; ResQ CPAP. This type of CPAP produces vibrations which acts in similar fashion to the waveforms produced by the high frequency ventilation. [10].

Bubble CPAP reduces the need for ventilation and eventually decrease the incidence of chronic lung disease [11,12]. Sufficient flow in the underwater blow off system creates continuous bubbling from the end of the underwater tube which ensures that circuit pressure is maintained. This type of CPAPs is inexpensive and straightforward with an added advantage that if there is inadequate pressure due to massive air leak, the bubbles ceases.

AIM

To study the clinical utility of non-invasive methods of ventilation such as continuous positive airway pressure (CPAP) in Respiratory Distress Syndrome (RDS) babies and to study their complications.

OBJECTIVES

1. To study use of CPAP in RDS.
2. To find out the complications of using CPAP.
3. To study the duration of hospital, stay with these methods.

MATERIALS & METHODS:

It was a descriptive longitudinal observational study conducted from September 2018 to September 2020 at Pravara Rural Hospital (PRH), LONI after obtaining approval from the ethical committee and written informed consent from the patients' relatives.

INCLUSION CRITERIA:

1. All preterm neonates with 30-37 weeks gestational age having clinical features of RDS with Silverman Anderson Score 4-7.
2. Preterm babies with RDS grade I & II who are already on CPAP.
3. Parents willing to participate in the study.

EXCLUSION CRITERIA:

1. Severe RDS of grade 3 and 4 by chest radiograph.
2. Preterms who are on ventilators as the primary mode of management with respiratory distress syndrome
3. Babies having any associated congenital heart defects

DATA COLLECTION:

All preterm newborns with gestational age of 30-37 weeks (by New Ballard Score) having RDS meeting the inclusion criteria were included in the study. Among these, patients with Respiratory Distress Syndrome having SAS score between 4-7 or hazy lung field were taken on blender CPAP. Complete maternal history and physical examination of the neonates were done and if features of RDS was found, baby were kept on early CPAP if the delivery was prior informed. If CPAP was not available or if it was not a planned delivery then complete neonate history was documented and shifted to NICU immediately and based on severity interventions like CPAP; surfactant delivery, mechanical ventilation was planned.

Where preterm with RDS 1st and 2nd grade showed no progression of disease, Fio2 requirement<40%, spo2 > 90% with minimum 5 PEEP, then CPAP was continued. If RDS has worsened and require Fio2 >40%, then surfactant was given by INSURE technique; followed by CPAP. Preterm with RDS showing progression of disease and not maintaining SPO2above 90% on CPAP or even after surfactant, were ventilated.

Bovine derived surfactant (SURVANTA or NEOSURF) in a dose of 4 ml/kg was used in our study. Early rescue is giving surfactant within 2 hours of birth and late rescue is giving surfactant after 2 hours of birth depending on the severity of baby and affordability of parents.

1. Early CPAP is the initiation of CPAP to preterm RDS baby within half an hour and late CPAP is after half an hour of birth. The conventional bubble CPAP with humidified oxygen with a blender (Fisher and Paykel) was used in our study where PEEP and Fio2 was adjusted according to need of patient.
2. The criteria for weaning was absence of respiratory distress (minimal or no retractions and respiratory rate between 30 and 60 per minute) and, SpO_2>90% on FiO_2 <30% and PEEP <5 cm of water. Infants were diagnosed to have failed CPAP and were started on mechanical ventilation when they: (*a*) remained hypoxic, i.e. SpO_2<87% despite FiO_2>70% and PEEP >7cm of water; (*b*) had severe retractions on PEEP >7cm of water; (*c*) had prolonged (>20 seconds) or recurrent apneas (>2 episodes within 24 hours associated with bradycardia) requiring bag and mask

ventilation; and, (*d*) had severe metabolic acidosis or shock requiring inotropic support (dopamine and or dobutamine) >20µg/kg/min. Infants failing CPAP in the first 1 week of life were considered to be CPAP failures. Surfactant and mechanical ventilation planned when:

- Low and unacceptable spo2 even on CPAP with PEEP >7 and FIO2>0.7
- X ray showing worsening of RDS
- Deterioration in SAS score
- Prophylactic surfactant in preterm <28 weeks of gestation

STATISTICAL ANALYSIS:

Descriptive statistics were used for quantitative variables (mean, standard deviation and 95% confidence interval, median with interquartile range) and for qualitative variables (absolute and percentage frequencies) continuous data were analyzed by students independent t-test (for parametric data) or Mann Whitney U test (for non-parametric test). Categorically data was analyzed by chi square or Fischer exact test with P value<0.05 was considered statistically significant.

RESULTS:

A total of 17427 inborn neonates were delivered of which 2832 (16.2%) were preterm of which 438 were admitted in NICU in view of RDS due to prematurity. Thus, incidence of RDS among live births is 2.5 % and 15.4% among preterm. Out of the 438 preterm RDS neonates admitted in NICU, 308 neonates belonged to RDS grades 3 and 4 and were below 30 weeks of gestation. Therefore, they were excluded from the study. Our study was then conducted on the remaining130 preterm neonates belonging to RDS grades 1 and 2 and above 30 weeks of gestation. 53.8 %(70) neonates with RDS were male and 46.2%(60) were female.

2.3% (3) neonates with RDS were less than 1000 g, 52.3%(68) were between 1000-1499 g, 43.1%(56) were between 1500-1999 g, 23%(3) were above 2000g. In our study, 3(2.3%) were extremely low birth weight, 68 (52.3%) were very low birth weight whereas 59 (45.4%) were low birth weight.

36.9%(48) neonates delivered had no maternal risk factors whereas 29.3% (38) had PIH, 14.7%(19) had abruption placenta, 11.6 % had PROM, 2.4% had Diabetes Mellitus. **(Figure 1)** No Antenatal steroids were given to 52.3% (68) preterm RDS deliveries, whereas 15.45%(20) received 1 dose of steroid ,30% (39) received 2 doses of steroids ,0.8%(1) received 3 doses and 1.5%(4) received complete 4 doses of steroids.

80.8% (105) premature neonates with RDS were not given surfactant and 19.2%(25) were given surfactant. 61.5%(80) preterm RDS neonates had Retinopathy of Prematurity(ROP) and 38.5%(50) had no ROP as complication. 57.7%(75) neonates had no sepsis,28.5 % (37) neonates had EOS and 13.8% (18) had LOS as complication.

43.8%(57) RDS neonates were given early CPAP and 56.2%(73) were not given early CPAP. **(Figure 2)**

Out of 130 preterm RDS neonates, only 10.8%(14) neonates received mechanical ventilation. 93.1% (121) preterm RDS neonates were having good prognosis and only 6.9%(9) neonates succumbed to illness. 79.2% (103) preterm RDS neonates had no nasal trauma and only 20.8%(27) had nasal trauma on CPAP. Average number of days on CPAP who had nasal trauma was 7.22 which is of significance with p<0.0001 than that of 3.2 who had no trauma on CPAP.

97 neonates managed only with CPAP, all had good outcome. Out of 19 neonates managed by CPAP+ surfactant,18(94.7%) had good outcome. Out of 6 neonates managed by CPAP+Surfactant+MV, 2(33.3%) had good outcome and 8 neonates were managed by CPAP+MV of which 4(50%) had good outcome. **(Figure 3 & 4)**

There was significant difference in outcomes of preterm RDS neonates according to mode of management with p value of less

than 0.0001. Out of 130 preterm RDS neonates, only 4.6% (6) developed Pneumothorax complication of which only 2 had mortality. Out of 130 preterm RDS neonates, only 1.5%(2) developed BPD as a complication. **(Figure 5)**

52.3% (68) deliveries were not given steroid prophylaxis of which 89.7% (61) had good outcome and 10.3% (7) had mortality. 47.7%(62) deliveries were given steroids of which 97.7%(60) had good outcome and only 3.3%(2) had mortality. It shows that antenatal steroids play an important role in reducing RDS severity and their outcome.

43.8%(57) preterm RDS neonates were given early CPAP and 56.2% (73) were given late CPAP. The success rate in case of early CPAP was 54 (94.7%), whereas in case of late CPAP, it was only 62(84.9%) out of 73. In early CPAP, 3 patients (5.3%) required surfactant and ventilation whereas in late CPAP 22 patients (30.1%) required surfactant and 11 (15.1%) required ventilation. Overall mortality in early CPAP was 3.5% whereas in late CPAP it was 9.6%. Outcome of preterm RDS neonates based on surfactant in early and late CPAP category has significant statistical difference with p-value 0.0008. In CPAP success cases, survival rate was high 99.1% (115) and mortality was only 0.9%(1) whereas in CPAP failure cases, survival rate was 42.9%(6) and mortality was 57.1%(8). Sepsis was high 85.7% (12) in CPAP failure and only 37.91%(44) in CPAP success and has significant statistical difference with p value 0.0002.

ROP was 60.3% (70) in CPAP success and 71.4% (10) in CPAP failure. PDA was 14.7% (17) in CPAP success and 14.3%(2) in CPAP Failure Only 1.7%(2) developed pneumothorax in CPAP success and 28.6%(4) developed pneumothorax among CPAP Failure cases. Outcome of preterm RDS neonates in CPAP success and failure cases is statistically significant with p value less than 0.0001. Pneumothorax also has significance in CPAP success and CPAP failure with p value of 0.001.

DISCUSSION:

In our study we found that the incidence of prematurity was 16.2% which was comparable with NNPD study whereas NICHD showed slightly lesser 9% may be due to good care provided to mother. The incidence of RDS in preterm was 15.4% which was comparatively less than NICHD (44%)and Saboute et al. (58.3%) as they considered neonates upto 1500 grams and upto 34 weeks of gestation. The incidence seen in our study was less as we had taken only grade 1 and 2 RDS and babies above 30weeks of gestation.

Table 1: Sex distribution

Study	Male neonates with RDS	Female neonates with RDS
Present study(2020)	53.8%	46.2%
Imani M et al[126] (2013)	62.5%	37.5%
M. Saboute et al[123] (2015)	61.9%	38.1%
Agrawal S. et al[125](2016)	51.4%	48.6%
Sanghvi A. et al[122] (2017)	59.6%	40.4%

In our study, there is male preponderance (53.8%) which is comparable with Imani M et al (62.5%), M. Saboute et al(61.9%), Agrawal S.et al (51.4%) and Sanghvi A. et al(59.6%). Males were affected more than females with RDS as epithelial sodium channel expression will be less in males.

RDS and Birth weight

In our study, (with reference to table no.7) birth weight 1000-1499 grams (VLBW) showed higher (52.3%) incidence of RDS which is comparable with NICHD (60%), M. Saboute et al (52.5%),Sanghvi et al (50.9%).In contrast Agarwal et al had higher number (83.9%) which is not comparable with our study may be as they included birth weight less than 1499 grams. Less than 1000 grams birth weight in our study was 2.3 % which is comparable with Sanghvi et al 5.2% .In contrast to our study NICHD showed 40%, Agarwal et al showed 16% with birth weight less than 1000 grams as these included only less than 1499 grams babies.

Table 2: RDS Risk Factors

Risk factors	**Present study**	**Agrawal S. et al [125]**	**Sanghvi et al [122]**
	(2020)	(2016)	(2017)
Prematurity	**100%**	100%	100%
Male sex	**53.8%**	51.4%	59.6%
LSCS delivery	**54.6%**	10.2%	28%
Maternal diabetes	**2.4%**		5.2%
Multipara	**52.3%**		3.5%

In our study, we found Preterm is high risk factor 100% for developing RDS which is comparable with Agarwal et al and Sanghvi. Male sex preponderance (53.8%) is also comparable with Agarwal et all (51.4%) and Sanghvi et al (59.6%). We have found multiparity 52.3% which is one of the risk factor as there were grand multi para and twins in our study.

Mode of management of neonates with RDS

In our study, 74.6% neonates were managed only with CPAP in our study ,14.6% required CPAP + surfactant ,4.6% required CPAP+ Surfactant + MV and 6.2% were managed with CPAP + MV

Other studies have included all grades of RDS and neonates <30 weeks of gestation therefore requirement of surfactant and mechanical ventilation is more than our study.

47.7% neonatal deliveries were given antenatal steroids and 43.85% RDS neonates were given early CPAP intervention in our study which is one of the reason for reduced number of invasive procedures like surfactant and mechanical ventilation in comparison to other studies.

Table 3: Variables of CPAP success in preterm neonates with RDS

Variables	**Present study**	**Imani M et al [126]**	**Agrawal S. et al [125]**	**Sanghvi et al [122]**
Study Year	(2020)	(2013)	(2016)	(2017)
	N=116(89.2%)	N=40(50%)	N=34(50%)	N=39(72.2%)
Birth wt. (gm)(mean ±SD)	1.47+/- 0.23	1345±542	1270±190	1360±289
Gestational Age (wk) (mean±SD)	32.6+/- .56	31.00±2		31.00±1.85

Mean duration of stay(day)	21.4+/-9.8		65.56±45.91 (hrs)	26.74±11.99
Male sex	55.25	62.5%		56.4%
Birth weight <1500gm 1500-2000	49.1 %			51.3%
Antenatal steroids Taken	57(49.1%)	69%	22(42%)	22(56.4%)
Delivery (C.S.-VD)	63-51	21-19		
Sepsis	43(37.1)		20(38%)	5(12.8%)
PDA	17(14.7)	6(15.0%)		3(7.7%)
Maternal Hypertension	35(30.2)			18(46.1%)
Death	1(0.9)	7(17.5%)		

CPAP success rate in our study (89.2%) was comparable with Sanghvi et al (72.2%) and both the studies that considered CPAP, CPAP +Surfactant as success showed higher than Imani et al (50%) , Agrawal (50%) who considered only CPAP as success and CPAP +Surfactant as failure.

In our study Mean duration of hospital stay (21.4+/-9.8) was comparable with Sanghvi et al (26.74+/-11.99). Whereas Agrawal. S (65.56+/-45.91) showed higher than our study as they included all grades of RDS and less than30 weeks of gestation whereas our study included only RDS grades 1 and 2 and more than 30 weeks of gestation.

Even though Sanghvi has included all grades of RDS and less than 30 weeks of gestation, its mean duration of hospital stay is lesser than that of Agarwal as it included less number of cases.

Sepsis in our study 37.1% was comparable with Agrawal S. et al 38%.In contrast, Sanghvi showed less 12.8% may be due to less number of cases.

Mortality (0.9%) in our study was less compared to Imani et al (17.5%) may be due to inclusion of less than 30 weeks of gestation.

NASAL TRAUMA:

In our study, 79.2% (103) preterm RDS neonates had no nasal trauma and only 20.8% (27) had nasal trauma on CPAP. Average number of days on CPAP who had nasal trauma was 7.22days which is of significance with p<0.0001 than that of 3.2days who had no trauma on CPAP.

Table 4: Outcome in CPAP success and failure cases

	Present Study		**M. R. Bassiouny Et Al [129]**		**Koti Et El [94]**	
	CPAP Success	CPAP Failure	CPAP Success	CPAP Failure	CPAP Success	CPAP Failure
Survival	**99.1%**	42.9%	92.5%	76.4%	97.6%	64.2%
Death	**0.9%**	57.1%	7.5%	23.6%	2.4%	35.8%
Total	**116**	14	27	17	42	14

In our study, survival rate in CPAP success was 99.1% and mortality is only 0.9%. Our survival rate is superior in this category than bassiouny et al (92.5%) and koti et al (97.6%). This may be due to the fact that we included all babies more than 30 weeks. In CPAP failure, we found 42.9% survival and 57.1% mortality. This is not comparable with M. R. Bassiouny et al and Koti et al, as they showed 76.4% survival, 23.6% mortality and 64.2% survival, 35.8% mortality respectively, this may be due to less number of neonates included by them.

From our study, we found Outcome of preterm RDS neonates in CPAP success and failure cases is statistically significant with p value less than 0.0001.

Table 5: Complications in CPAP Success and CPAP Failure

	Present Study		**M. R. Bassiouny Et Al [129]**		**Koti Et El [94]**	
	CPAP Success %	CPAP Failure %	CPAP Success %	CPAP Failure %	CPAP Success %	CPAP Failure %
PDA	**14.7**	15	42	53	11.9	35.7
Sepsis	**37.9**	85.7	31	88	4.7	35.7
ROP	**60.3**	71.4	4	23		
Pneumothorax	**1.7**	28.6			4.7	0

In our study, in CPAP success cases, PDA 14.7% of the study was comparable with Koti et al (11.9 %) while in M. R. Bassiouny et al it was 42%. Sepsis 37.9% was comparable with M. R. Bassiouny et al 31%whereas it was lesser in Koti et al 4.7% as number of cases was significantly less than our study. Pneumothorax 1.7% was comparable with 4.7% Koti et al.

All 3 studies show that complications like PDA, Sepsis, ROP were more in CPAP failure cases than in CPAP success cases.

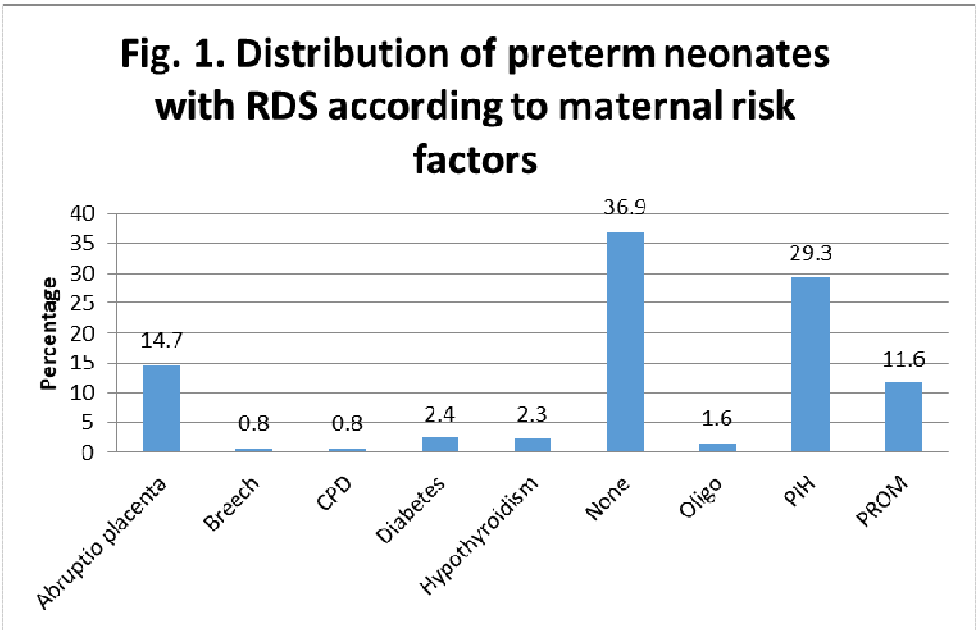
Pneumothorax was more in CPAP failure cases (28.6%) than CPAP success cases (1.7%) in our study with significant p value of 0.0001 due to requirement of mechanical ventilation in CPAP failure cases.

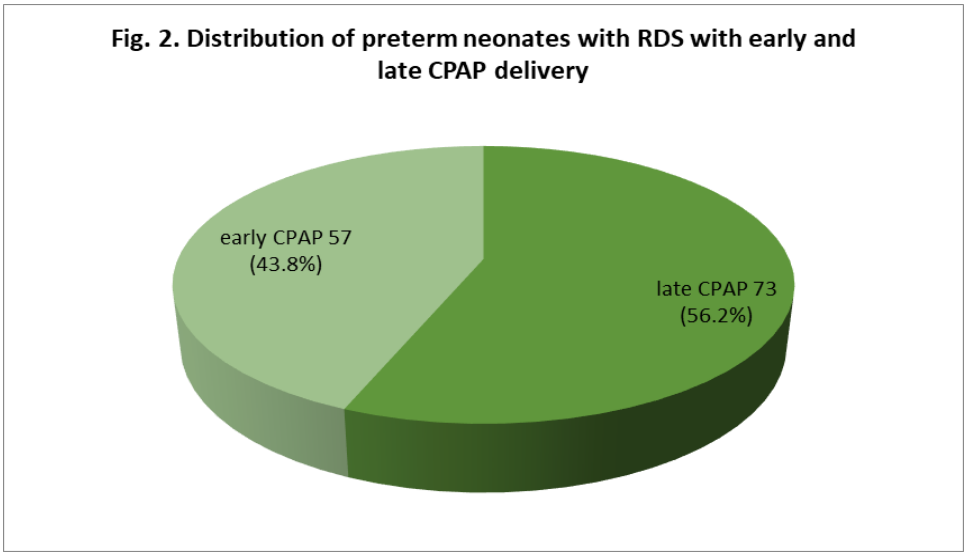
Paradoxically, Pneumothorax was more in CPAP success cases then CPAP failure cases in Koti et al may be due to lesser CPAP failure cases in this study.

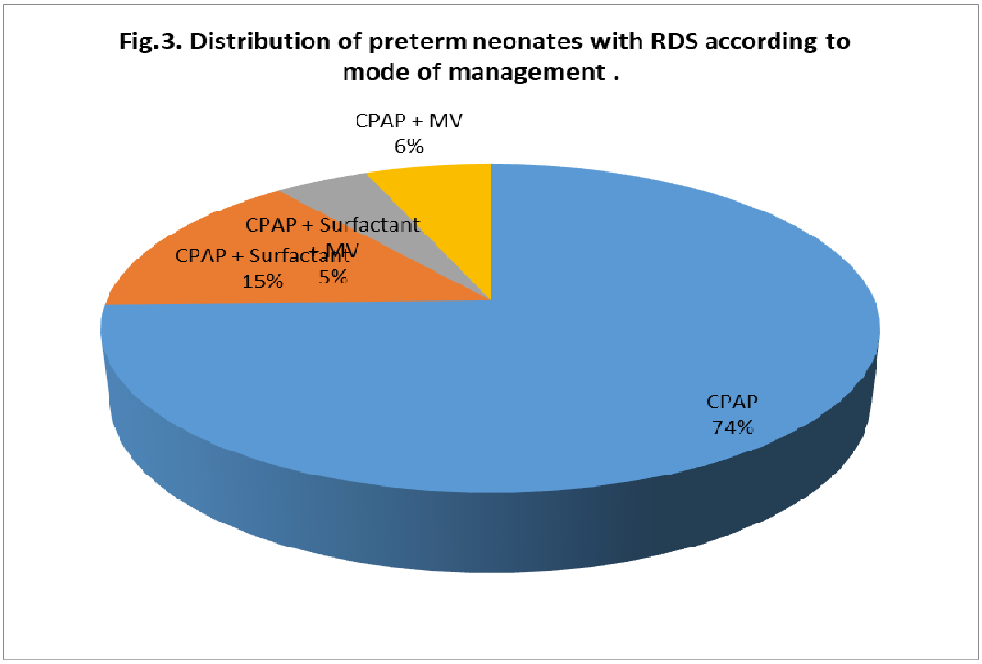
There was a statistical significant difference of sepsis and pneumothorax complications among CPAP success and failure cases with p value of 0.002 and 0.0001 respectively.

Table 6: Relation of Surfactant, Ventilation and Mortality in Early and Late CPAP

	Present study		**Ravindra Kumar Jain Et Al [93]**	
	Early	**Late**	**Early (25)**	**Late (47)**
Surfactant given	5.3%	30.1%	32%	46.8%
Ventilated	5.3%	15.1%	16%	14.9%
Mortality	3.5%	9.6%	13.4%	14.9%







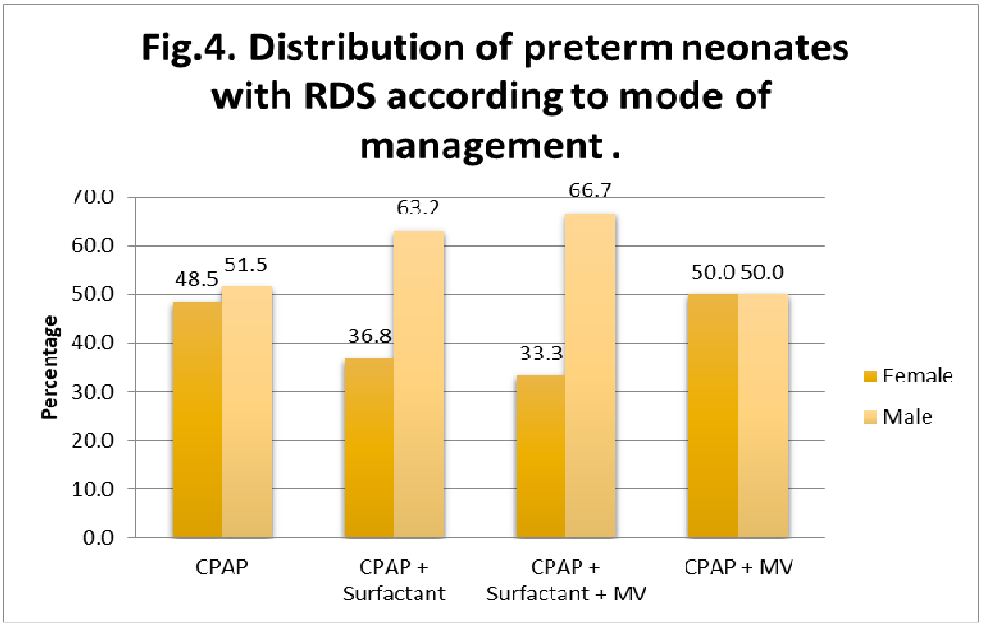
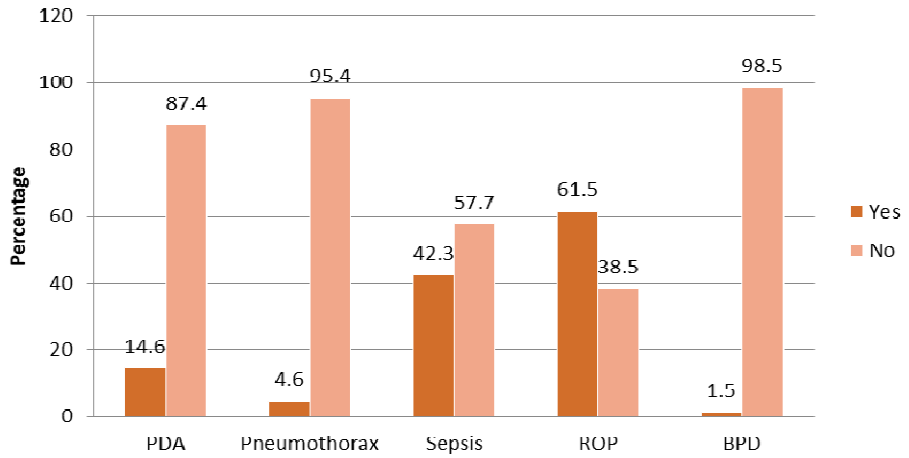


Fig. 5. Complication in preterm neonates with RDS



In our study (concerning table no.25) we gave surfactant to 5.3% of neonates with early CPAP whereas 30.1% received surfactant with late CPAP. In early CPAP we ventilated all (5.3%), mortality was 3.5% and in late CPAP 15.1% were ventilated and 9.6% had mortality. Ravindra Kumar et al ventilated more in both groups (early 16%, late 14.9%) and mortality was more (early 13.4%, late 14.9%). This less mortality and ventilation in our study may be due to we included neonates above 30 weeks of gestation. The mean duration of Hospital stay was more in the Late CPAP (18.86 days) than in the Early CPAP(22.81days) category.

From our study there was no statistically significant difference in CPAP success and CPAP failure

Among the early and late CPAP group but there was statistical significant in surfactant and ventilation in early and late CPAP group.

Survival rate (93.1%) in our study was comparable with Koti et al (89.2%), Ravindra Jain et al (87.5%), Sanghvi et al (85.9%) and Imani et al (86.3%). In contrast to our study Ghafoor et al (56.4%) and M Saboute et al (63.9%) had less survival rate as they had included RDS neonates below 30 week of gestation. Mortality was 6.9% in our study compared with Sanghvi et al 8.8%, Koti et al 10.8% whereas other studies Ravindra Jain et al 12.5% Ghafoor et al 43.6%, Imani et al 13.7% and M Saboute et al 36.1% had higher mortality. 47.7% of mothers were given antenatal steroids (Concerning table no.2) and 43.85% of RDS neonates were given early CPAP intervention in our study, which is one of the reasons for reduced number of invasive procedures like surfactant and mechanical ventilation in comparison to other studies thereby increasing survival rate and reducing mortality.

CONCLUSION:

Antenatal steroids not only play a role in reducing the severity of RDS but also in their good outcome. Complications like Nasal trauma and pneumothorax were less with early CPAP due to early recovery and less number of days on CPAP. Early CPAP in comparison to late CPAP has a maximum survival rate, minimum mortality rate, less requirement of surfactant and ventilation support and the CPAP success rate was high. So early neonatal steroid prophylaxis and early CPAP are

recommended for Preterm RDS Neonates in our study.

Conflict of interest: None

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