

## CLINICAL STUDY OF NEONATES RECEIVING OXYGEN THERAPY AND THEIR OUTCOMES

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### Abstract

**Background:** To identify maternal, perinatal and clinical factors in neonates needing oxygen therapy afterbirth. To observe relation between pulse oximetry (SpO<sub>2</sub>) and ABG (SaO<sub>2</sub> and PaO<sub>2</sub>). To observe outcome in the babies (Survived or Expired) and identify factors associated with outcomes. **Materials and Methods:** The study was approved by IEC. Design is Prospective cohort study. Population is neonates needing oxygen therapy. Inclusion criteria is neonates born in DR.PSIMS &RF getting admitted with need for oxygen therapy. Exclusion criteria is neonates born outside. Sample & Duration is 300 consecutive neonates needing oxygen therapy until Discharge or death. Study period are 2 years. Variables measured is numerous maternal, perinatal and baby variables were noted. Methodology is data collected and analysis was performed. **Result:** The prevalence of prematurity is 35%. The proportion of severely depressed babies who needed intubation is 13.3% and who needed chest compressions is 6%. About 30% needed oxygen therapy and bag and mask ventilation. The common clinical problems are jaundice (a marker of sepsis) in 42.7%, pneumonia in 41.3%, perinatal asphyxia in 27.1%, sepsis in 20.4%, prolonged APTT in 17.3% and prolonged PT in 9.1% and bleeding diathesis in 16%. 7 to 27% babies needed CPAP and /or ventilatory support. **Conclusion:** The correlation between SpO<sub>2</sub> by pulse oximetry and SaO<sub>2</sub> by blood gas analysis is ranging from r value of 0.4 to 0.8. Pulse oximetry looks satisfactory in monitoring the oxygenation status. The risk factors for mortality are: Babies needing interventions (oxygen, bag and mask, endotracheal tube intubation, chest compressions, epinephrine and intravenous fluids) are having higher risk of death (OR8.24) Neonates with shock have higher risk of death (OR9.75) Prolonged PT is associated with higher risk of death (OR17.24). Mothers requiring antenatal steroids is associated with higher risk of death of neonates (OR8.42). Failure to start Breast feeding is associated with higher risk of mortality (OR130.1). Mechanical ventilatory support is associated with higher risk of death (OR37.3).

## INTRODUCTION

Oxygen administration is a common therapy in neonatal nurseries.<sup>[1]</sup>

Many neonates who get admitted in SNCU OR NICU receive oxygen therapy. Common clinical situations in which baby needs oxygen:<sup>[2]</sup>

1. Need for resuscitation atbirth
2. Birthasphyxia
3. Respiratorydistress
4. Hypoxemia (SpO<sub>2</sub> <87% or paO<sub>2</sub> <50 mm of Hg) in roomair
5. Cyanosis
6. Hypothermia
7. Recurrent apneicattacks

Hypoxemia as well as hyperoxemia are harmful. SpO<sub>2</sub> alone is not always indicative of adequacy of oxygen therapy.<sup>[3,4]</sup>

The incidence of oxygen therapy is dependent on gestational age at birth with 97% of 7-27 weekers receiving supplemental oxygen, whilst 79% of 28-31 weekers receive oxygen therapy during their initial hospitalisation.<sup>[5]</sup>

If one could identify the preventable risk factors it would help to anticipate and intervene early for a better outcome.

Outcome depends not only on optimum oxygen therapy [SpO<sub>2</sub> 88-92% with lower and upper limits 85-95%] but also on clinical condition and biological maturity. Usual relation between SpO<sub>2</sub> and paO<sub>2</sub> is as follows.<sup>[6-8]</sup>

Though there is an approximate relation between SpO<sub>2</sub> and paO<sub>2</sub>, paO<sub>2</sub> always cannot be accurately

predicted from SpO<sub>2</sub>.<sup>[9]</sup> In our situation where continuous paO<sub>2</sub> monitoring is not feasible, there is a need to observe reliability of continuous SpO<sub>2</sub> monitoring in maintaining optimum paO<sub>2</sub>.

| Oxyhemoglobin saturation (SpO <sub>2</sub> ) | PaO <sub>2</sub>   |
|--|--------------------|
| 0 to 85%                                     | 0 to 45 mm of Hg   |
| 85 to 95%                                    | 45 to 65 mm of Hg  |
| 95 to 100%                                   | 65 to 500 mm of Hg |

### Aims and Objectives

- To identify maternal, perinatal and clinical factors in neonates needing oxygen therapy afterbirth.
- To observe relation between pulse oximetry (SpO<sub>2</sub>) and ABG (SaO<sub>2</sub> and PaO<sub>2</sub>).
- To observe outcome in the babies (Survived or Expired) and identify factors associated withoutcomes.

## MATERIALS AND METHODS

The study was started after the protocol was approved by institutional ethics committee. Informed consent from the parent/legal authorized guardian is obtained. Design of the study: Prospective cohort study.

**Population:** Neonates needing oxygen therapy.

### Inclusion Criteria

Neonates born in DR. PSIMS & RF and getting admitted to NICU with a need for oxygen therapy.

### Exclusion Criteria

Neonates born outside.

**Sample size:** 300 consecutive neonates needing oxygen therapy.

**Follow up duration:** Discharge or Death after starting O<sub>2</sub> therapy.

**Study period:** November 2014 to October 2016.

**Variables measured:** Various maternal, perinatal and baby variables were recorded.

**Methodology:** A detailed case history was taken, general and systemic examination were performed. The observations were noted.

### Statistical Analysis

The data was entered into case proforma and converted into

**Electronic database:** Statistical analysis was done using Epi Info TM 7.1.5.2 and Medcalc15.11.4, Belgium.

## RESULTS

Among the mothers of neonates receiving oxygen therapy about 13.33% have preeclampsia, 12.89% have gestational hypertension, 6.22% have hypothyroidism, 3.11% have eclampsia and Gestational diabetes mellitus in 2.22%.

The prevalence of anemia, asthma, eclampsia, GDM and epilepsy are low.

About 36.6% mothers needed antenatal steroids showing the suspicion of premature labor.

Babies delivered by Caesarean section are 46.22% among which 31% are by emergency cesarean sections. About 54% are vaginal deliveries.

Fetal distress is observed in 6.22% of babies, PROM in about 9.8% and PPROM in about 6%. MSAF was observed in 24% of the babies.

The median APGAR score at 1 minute is 6. Score at 5 minute is 7 and at 10 minutes is 9.

Out of 4 babies with APGAR recorded at 15 minutes, 2 babies who survived are having a score of 10 and 9 respectively and other 2 babies who expired are having scores 0 and 3 respectively.

About 30.67% required bag and mask ventilation, 13.33% required intubation, 5.78% required chest compressions, 1.78% required epinephrine at birth.

The median gestational age of babies receiving oxygen therapy is 38 weeks, and median weight being 2610 grams. This implies that a significant number of term and normal birth weight babies needed admission for oxygen therapy.

The median age at admission in these babies is 1<sup>st</sup> hour of life.

Sepsis is found in 20% of babies among the study population with bacterial sepsis accounting for majority (97.73%).

The common clinical problems in neonates are jaundice (42.67%), pneumonia (41.33%), perinatal asphyxia (26.67%), sepsis (20.44%) followed by prolonged activated partial prothrombin time (17.33%), bleeding diathesis (16%), DIC (11.56%).

The common supportive therapies needed by the babies among the study population are phototherapy in 49%, CPAP in 26.67%, platelet transfusions in 18%, FFP transfusions in 15% and The common supportive therapies among the study population are phototherapy in 49%, CPAP in 26.67%, platelet transfusions in 18%, FFP transfusions in 15% and mechanical ventilation support in 7%.

There is a significant difference in gestational age between the survived and expired groups. Median gestational age in survived is 38 weeks (95%CI 38 to 38 weeks) and in expired group is 35 weeks (95%CI 32.1 to 37 weeks)

There is a significant difference in Birth weights between the survived and expired groups. Median birth weight in survived group is 2640 grams (95% CI 2560 to 2734 grams) and in expired group is 2055 grams (95%CI 1261.7 to 2533grams).

Babies who did not need CPAP, mechanical ventilator support, phototherapy are having decreased mortality, when compared to those who require them with odds ratio 0.38 (95%CI 0.15 to 0.93), 0.02 (95%CI 0.004 to 0.11), 4.88 (95% CI 1.82 to 15.19) respectively.

Babies in whom breast feeding could be started have more survival chance, when compared to babies in whom breast feeding could not be initiated, with odds ratio 48 (95% CI 15.3 to 162.1).

The first ABG done at a median age of 4.5 hours of life shows a significant difference in the SaO<sub>2</sub> values between expired (94.4%, 95% CI 84.1% to 96.8%) and survived (97%, 95% CI 96% to 97.7%).

This shows that babies' survival is significantly more when ABG done at median age of 4 hours has SaO<sub>2</sub> between 96% and 98%.

In the cohort of neonates receiving oxygen therapy the case fatality rate is 14.1% (95% CI 9.8% to 19.6%).

On multivariate logistic regression analysis the factors associated with risk of death in babies receiving oxygen therapy are delivery room interventions (oxygen, bag and mask, endotracheal tube intubation, chest compression, epinephrine, intravenous fluids) with odds ratio 8.24 (95% CI 1.77 to 38.36), shock with Odds ratio 9.75 (95% CI 0.79 to 119.38), prothrombin time prolongation with Odds ratio 17.24 (95% CI 2.38 to 124.83), antenatal steroids 2<sup>nd</sup> dose to mothers odds ratio 8.42 (95% CI 1.67 to 42.44), Breast feeding could not be started, odds ratio 130.06 (95% CI 20.01 to 845.28) and requiring mechanical ventilation support with odds ratio 37.33 (95% CI 2.25 to 617.77).

The SpO<sub>2</sub> values recorded at median age of 4 hours are correlating with ABG SaO<sub>2</sub> and PaO<sub>2</sub> done at same time.

The second SpO<sub>2</sub> Values recorded at median age of 27.7 hours of life are correlating with corresponding ABG SaO<sub>2</sub> and PaO<sub>2</sub>.

Similarly the third SpO<sub>2</sub> recorded at median age of 58 hours is correlating with the ABG SaO<sub>2</sub> and PaO<sub>2</sub>. The degree of correlation between SpO<sub>2</sub> and ABG values is having increasing trend when observed from 4 hours to 60 hours of life.

## DISCUSSION

In this prospective cohort study of 225 neonates, who received oxygen therapy during their stay in NICU of rural teaching hospital, the following observations are made and compared with available literature:

Maternal problems observed during pregnancy in our study are preeclampsia (13.3%), gestational hypertension (12.9%), hypothyroidism (6.2%), eclampsia (3.1%), and gestational diabetes mellitus (2.22%).

In our study the proportion of gestational hypertension is similar to other studies.<sup>[10-19]</sup>

The proportion of preeclampsia is higher in Nilufure et al,<sup>[14]</sup> and Bahubaligane et al,<sup>[18]</sup> study and lower in Hafiz et al,<sup>[16]</sup> study when compared with our study.

Other studies are reporting higher proportion of gestational diabetes mellitus compared to our study.

The proportion of mothers receiving antenatal steroids is 36.6% indicating the proportion of premature labor suspected by obstetrician. This is corresponding to the proportion of preterm babies in our study which is 35%. These observations indicate high proportion of preterm deliveries in our population, when compared with WHO prevalence of preterm deliveries in low income countries like India is 12% (range 5 to 18%).

The prevalence of preterm babies in our study is 35% is similar to that of the other studies above.<sup>[14-16,19,20]</sup>

Natal problems observed in our study are meconium stained amniotic fluid (24%), PROM (9.8%), fetal distress (6.2%) and PPRM (6%).

## Delivery room factors and clinical factors in neonates receiving oxygen therapy

The median Apgar score at 1 minute is 6, at 5 minute is 7 and at 10 minutes is 9.

In our study the 1 minute APGAR is 6 which is below the observations suggested value in a normal newborn baby (About 90% of normal term newborns have an APGAR between 8 and 10 during their first breath in first 10 seconds) and it showed improvement by 10 minutes.

Nevertheless, 30% of babies needed oxygen in delivery room, about 30.7% required bag and mask ventilation in delivery room and later all the 225 babies needed oxygen therapy in NICU.

So in our population APGAR scores up to 10 minutes still may be of use for exercising caution despite normal pulse oximetry readings.

The proportion of severely depressed babies in delivery room is 13.3% as indicated by the requirement for endotracheal tube intubation and 6% requiring chest compressions.

The common clinical problems identified in these babies are jaundice (42.67%), pneumonia (41.33%), perinatal asphyxia (26.67%), sepsis (20.44%) followed by prolonged activated partial prothrombin time (17.33%), bleeding diathesis (16%) and DIC (11.56%).

Jaundice per se is not the primary disorder. It is most likely a part of sepsis because no hemolytic anemia or other reasons could be found in these babies. Among them 20.4% have culture proven sepsis and remaining 23% are most likely due to clinical sepsis. The proportion of very seriously ill neonates in our study is from 7% to 27% as indicated by the requirement of CPAP and ventilator respectively.

Oxygenation status by pulse oximetry and arterial blood gas analysis in babies receiving oxygen therapy:

In our study at 4 hours, 27.7 hours, 60 hours the SpO<sub>2</sub>, SaO<sub>2</sub> and PaO<sub>2</sub> corresponding values:

In our study the correlation between SaO<sub>2</sub> and SpO<sub>2</sub> is ranging from r values of 0.4 to r value of 0.8.

Though correlation values are low to moderate, all the values of SpO<sub>2</sub> and SaO<sub>2</sub> are within normal range. But the previous studies done in sick newborns show that pulse oximetry values were highly correlated with measured SaO<sub>2</sub> values; values of 92 ± 3% were associated with PaO<sub>2</sub> values of 45 to 100 mm of hg.<sup>[23,29]</sup>

In the studies by other investigators Jung Hwan choi et al, Deckardt and Steward, 1984; New, 1985; Durand and Ramanathan, 1986; Harris et al. 1986; Ramanathan et al. 1987; Jennis and Peabody, 1987; House et al. 1987; Fanconi, 1988 there is very good linear relationship between simultaneous pulse oximetry SpO<sub>2</sub> and measured SaO<sub>2</sub> by co-oximeter (r=0.9).<sup>[21-28]</sup>

## Risk factors associated with mortality in neonates receiving oxygen therapy:

Antenatal steroid need to the mother in our study is found to be a risk factor for neonatal mortality on

multivariate analysis. The risk of baby dying is associated with mother receiving 2 doses of steroid. This can be explained by the higher degree of prematurity in those babies

In our study by Kruskal-wallis test the median gestational age of babies of mothers who received first dose of steroid is 33 weeks, the median gestational age of babies of mothers who received 2nd dose of steroid is 35 weeks and median gestational age of babies of mothers who received no steroids is 38 weeks.

In post hoc analysis there is significant difference between gestational age of babies of no steroid mothers and other 2 groups (1st dose and 2nd dose) but not between gestational age of 1st dose and 2nd dose babies.

But gestational age is not found to be a risk factor on multivariate analysis.

This shows that prematurity per se is not mainly responsible for mortality but the complications like DIC, prolonged prothrombin time, shock, encephalopathy associated with prematurity are responsible for mortality.

The lesser mortality in MSAF group compared to clear amniotic fluid group is likely to be due to following reasons:

1. Probably there are factors other than MSAF which are responsible for mortality.
2. MAS babies who are more mature, when taken appropriate clinical care, are likely to survive compared to clear amniotic fluid group babies with prematurity and its associated complications like DIC, prolonged PT, sepsis, encephalopathy.

In the clear amniotic fluid group more preterm babies are found. Their gestational age ranges from 28 to 42 weeks where as in meconium-stained amniotic group gestational age is ranging from 35 to 41 weeks.

Babies who did not require delivery room care (oxygen, bag and mask, intubation, chest compression, epinephrine, intravenous fluid) are 0.3 times (95% CI 0.1 to 0.6; p value 0.002) less likely to die when compared to babies who needed these interventions.

The babies who needed delivery room care are 8.2 times more likely to die when compared to those who did not require these interventions.

APGAR at 1 minute is significantly lower in expired group (score 3.5) compared to survived group (score 6). APGAR at 5 minute is also significantly lower in expired group (score 6.5) compared to survived group (score 7). APGAR at 10 minute is also significantly lower in expired group (score 8) compared to survived group (score 9).

The SpO<sub>2</sub> at 1 minute, 5 minutes and 10 minutes showed a significant difference between the survived and expired groups.

The median SpO<sub>2</sub> 1 minute in survived group is 74% (95% CI 72% to 75%) where as in expired group is 65% (95% CI 60.4% to 67.8%).

The median SpO<sub>2</sub> at 5 minutes in survived and expired groups is 85% (95% CI 85% to 85.1%) and 77% (95% CI 72.7% to 80.0%) respectively.

The median SpO<sub>2</sub> at 10 minutes in survived group is 93% (95% CI 92% to 94%) and expired group is 88% (95% CI 82% to 90.4%).

The overall case fatality rate (Nonspecific /crude CFR) in the babies receiving oxygen therapy in our study is 14.15%.

In swarnakaret al,<sup>[12]</sup> study in neonates with respiratory distress the case fatality rate is 22.86%.

On multivariate logistic regression analysis the factors associated with risk of death in babies receiving oxygen therapy are interventions like oxygen therapy, bag and mask, intubation and chest compressions, epinephrine and intravenous fluid with odds ratio 8.24 (95% CI 1.77 to 38.36). Shock with OR 9.75 (95% CI 0.79 to 119.38), Prothrombin time prolongation with OR 17.24 (95% CI 2.38 to 124.83), Antenatal steroids 2nd dose odds ratio 8.42 (95% CI 1.67 to 42.44), Breast feeding could not be started odds ratio 130.06 (95% CI 20.01 to 845.28), Requiring mechanical ventilator support with odds ratio 37.33 (95% CI 2.25 to 617.77).

These observations suggest that in babies receiving oxygen therapy there are other factors that influence the mortality. When these factors are anticipated/identified early, better and focused care to those babies with these risk factors can be given.

## CONCLUSION

In this prospective cohort study of 225 neonates admitted in NICU of rural teaching hospital receiving oxygen therapy the following are the important observations

1. Common maternal problems during pregnancy are preeclampsia (13%), gestational hypertension (13%). The proportion of mothers received antenatal steroids is 36.6%.
2. The prevalence of prematurity among these admitted babies is 35%.
3. The proportion of severely depressed babies who needed endotracheal tube intubation in delivery room is 13.3% and 6% of delivered babies needed chest compression in delivery room. About 30% of babies needed oxygen therapy and bag and mask ventilation in delivery room.
4. The common clinical problems encountered are jaundice (a marker of sepsis) in 42.7%, pneumonia in 41.3%, perinatal asphyxia in 27.1%, sepsis in 20.4%, prolonged APTT in 17.3% and prolonged PT in 9.1% and bleeding diathesis in 16%.
5. The properties of seriously ill to very seriously ill neonates during their stay in NICU is 7 to 27% who needed CPAP and or ventilator support.
6. The correlation between SpO<sub>2</sub> by pulse oximetry and SaO<sub>2</sub> by blood gas analysis is ranging from r value of 0.4 to 0.8. Nevertheless, the median SpO<sub>2</sub> by pulse oximetry is 97% to 98%. Hence pulse oximetry looks satisfactory in monitoring the oxygenation status of neonates.

7. The risk factors for mortality among babies receiving oxygen therapy are:
  - Babies needing delivery room interventions (oxygen, bag and mask, endotracheal tube intubation, chest compressions, epinephrine and intravenous fluids) are having higher risk of death (OR8.24)
  - Neonates with shock have higher risk of death (OR9.75)
  - Prolonged prothrombin time is associated with higher risk of death (OR17.24)
  - Mothers requiring antenatal steroids is associated with higher risk of death of neonates (OR8.42)
  - Breast feeding when could not be started due to the clinical condition is associated with higher risk of mortality (OR130.1)
  - Needing mechanical ventilation support is associated with higher risk of death (OR37.3)
8. The identification of the risk factors associated with mortality in this population of babies will help in future reduction of mortality by focused and closely monitored care to such group of babies.

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