Reduction of Inappropriate Use of Oxygen by Standardizing Initiation of Simple Check List among Neonates Admitted in Newborn Care Unit: A Quality Improvement Initiative

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Abstract
Introduction: Preterm and term infants are more frequently exposed to high concentrations of oxygen for prolonged periods. When supplemental oxygen is needed for care, it will be prudent to avoid fluctuations in SpO₂. The definition of the safest level of oxygen saturations in the neonate remains an area of active research. On the basis of the recently published evidences, the most suitable approach would be to set an alarm limits between 90 and 95%.

Objective: To reduce the inappropirate use of O₂ (concentration and duration) by implementation of standard protocol, which is done by quality improvement strategy.

Materials and Methods: This is a quality improvement study conducted in a tertiary care children’s health institution in India. Pre interventional and post interventional data are collected from hospital records of 69 and 101 hospitalized newborn cases respectively. By Q.I method, first prioritization of problem and research team formation, then clear aim statement about study is discussed prior to data collection. In 2nd step analysis of problems and the team members tried to solve this problem by using the fish bone analysis method. Then the changes are made as per PDSA cycle (CME about implementation of new protocol, reorientation of staffs, some changes made in emergency department. Initially smaller changes then multiple and larger events done). The final data are analyzed and compare with baseline data.

Results: There reduction of duration and concentration of O₂ use is observed as < 2 days duration in final data i.e 69.7% which is significantly more than base line data (23%). Appropriate use of O₂ among neonates is significantly increased after implementation of quality improvement strategy (67.96%) over base line data (19%). In final data mean O₂ therapy is 1-2 days in comparison with base data i.e 3-5 days. There are no significant changes in outcome parameters.

Conclusion: Practice recommendation of O₂ saturation targets newborn cared with minimizing oxygen therapy and toxicity.

Keywords: Oxygen, newborn, SPO₂, preterm, free radicals.

Introduction
Oxygen is very essential in newborn health care because many conditions that affect babies in the first days of life which can result in low levels of oxygen in the body. Hypoxemia is a life-threatening condition that results in increased mortality and morbidity among neonates. Prematurity and respiratory distress syndrome (surfactant deficiency), pneumonia and other severe infections, asphyxia and difficulties in the transition from foetal to neonatal life can all result in hypoxemia. Supplemental oxygen is an essential lifesaving treatment during this period[1]. The therapeutic use of oxygen in neonatal period is considered as double edged sword because of its beneficial and toxic effects. During the 1st month of life, hyperoxia, inflammation, episode of hypoxia–reoxygenation
and free iron are appear to be the sources of increased ROS release which may cause tissue injury. Oxidative stress in neonates is mainly due to decreased antioxidants and increased reactive oxygen species (ROS), or both. Studies reported that antioxidant capacity, in preterm newborns is lesser than term babies. The mechanisms of ROS generation are: mitochondrial respiratory chain, free iron and Fenton reaction, inflammation, hypoxia and/or ischemia, reperfusion, and hyperoxia[2]. Oxidative stress due hyperoxia has been recognized to be responsible for generalized tissue damage and in particular causes injury to lung, CNS, retina, red blood cells. When supplemental oxygen is needed for new born care, it should be prudent to avoid changes and fluctuations in SpO₂. The definition of the safest level of oxygen saturations in the neonate remains an area of active research[3]. Current WHO recommendations and clinical guidelines address several aspects of oxygen therapy. Clinical indications for oxygen use include resuscitation of preterm infants and advanced resuscitation of term infants as well as the full spectrum of respiratory illness from mild hypoxemia to moderate/severe respiratory distress and respiratory failure[4].

Currently, on the basis of the published evidences, the most suitable approach would be to set alarm limits between 90 and 95%. It should allow to avoid SpO₂ values associated with potential hypoxia and/or hyperoxia as the risk of tissue damage due to oxidative stress in perinatal period should not be underestimated[5]. Other study in New Zealand reported that there was heterogeneity for mortality between the original oxygen saturation algorithm and the revised algorithm which resulted in clearer separation of the groups. The peak median saturation for infants receiving supplementary oxygen is 89% vs 92%[6].

In most of the health facilities in India, WHO - guide line is not followed and over dose of O2 used irrationally which lead to several disease conditions leading to increased morbidity and mortality. At the same time the available resources are used unnecessarily without indication and create a scarcity during emergency requirement. So there is a definite gap between requirement and utilization which lead to economic loss with the cost of precious lives of neonates of our country[7].

On this back ground this study was conducted to evaluate the effectiveness of reduction of inappropriate use of Oxygen by standardizing initiation of simple check list among neonates admitted in newborn care unit by a quality improvement study.

Aim
To reduce irrational use of oxygen in new born unit among sick neonates by using quality improvement method.

Objectives
- Assessment the need of O2 therapy as per O2 requirement protocol (pulse-oxymetry)
- Assessment of duration and amount of O2 therapy in sick neonates in practice.
- Comparison of base line data and final data of various parameters and outcome before implementation of new QI strategy.

Materials and Methods
This was a QI (quality improvement) study conducted in the newborn unit (casualty, newborn word, ACRC (advance care resource centre) and SNCU (special newborn care unit) of pediatrics IPD of a tertiary health care center in India from 1st June to 31st July, 2018. This study protocol was approved by IEC of this institution. This study was conducted as per POCQI (point of care quality improvement) model 1. Identify problem, forming team and write an aim statement. 2. Analyze the problem and majoring quality of care. 3. Developing changes and testing it.4. Sustaining improvement. This project was planned in 3 phases, such as 1. Baseline Data collection (preintervention) phase for 7 days, 2. Implementation (orientation of changes) phases for1 month and 3. Final data collection phase for 7 days. For this study a QI team is constituted by including 1 associate professor( team leader), 2 assistant professors, 4 post graduate students,3 nursing staffs in charge of different sections of NBU. Graveness
of the protocol discussed amongst the team members. A CME conducted in the department on QI project as per POCQI model. Awareness on issues on O2 therapy discussed and guide lines on O2 recommendation are discussed. Base line data collection and analysis of data (% uses of O2, risk analysis, % of decreases O2 uses and outcome majors and plotted in flow chart. Then majors taken to decrease the uses of O2, awareness related to O2 therapy and toxicity, work place up gradation as per fish bone analysis and changes made as per PDSA(plan, do, study, act) cycle. This new plans and changes made are reflected in emergency. Comparison of final data with base line data done then multiple changes in the PDSA cycle done as per pros and cons. Negative results abounded and positive results are accepted. A total of 69 cases in pre intervention phase and 101 cases in intervention phase are included in the study. New born cases 0-1month of age, all the sexes, receiving oxygen therapy are selected.

**O2 Therapy Recommendation**

Newborn with hypoxemia closely monitored by pulse-oxymetry (<90%). O2 therapy will be discontinued in a chronically stable newborn. Stop O2 therapy when SPO2 >90%, O2 to be discontinued for 15 minute then newborn look for clinical signs of hypoxemia and spo2 level. Target O2 saturation done by using alarm limit. Observation of O2 saturation for 2-3 seconds and make O2 adjustment for stable saturation level for 3-5 minutes. It also observed if target not reaching at appropriate level give extra O2 supply. If SPO2 level stable for 30 minute stop O2 supply. An attempt for weaning then decrease nasal flow of O2 to 0.5 litre/minute, then discontinue the O2 supply[8][9].

**Study Procedure**

At beginning of the study there is a discussion among senior faculties with team leader based on their experience in their facility to prioritizing the problem on 4 important points such as important to patient outcome, affordable in terms of time and resources and easy to measure[10].

Data collection procedure: Data are collected in a predesigned format. The base line data regarding various aspect of oxygen therapy like whether recommended as per oxygen guide lines protocol (emergency signs, priority sign and less specific sign), duration of O2 therapy and outcome were collected[4]. Emergency signs if any like obstructed or absent breathing, severe respiratory distress, cyanosis, signs of heart failure, signs of shock, severe sepsis, heart rate with weak pulse (>= 160/m & <=100/min), low or unmeasurable BP (systolic<40mmhg), coma (very low level of consciousness GCS<=8), convulsion, signs of severe dehydration H/O diarrhea(any two signs) are noted. Priority signs if any are also recorded such as premature, temp hypothermia and or hyperthermia, trauma or other urgent condition, pallor (Severe), respiratory distress, signs of hypoglycemia, SPO2<90%, central cyanosis, nasal flaring, inability to drink or feed (Respiratory distress), grunting with every breath, depressed mental status –drowsy, lethargy etc. Less specific signs if any are also recorded such as severe lower chest in drawing, respiration rate >=70/m, head nodding synchronous with respiration, notable birth asphyxia (APGAR Score<=3), TTN, HMD, MAS, hypoglycemia, sick prematurity, apnea of primary bradycardia <100/min, apnea pathological and hypoventilation, birth weight<1.5kg, gestational age <32 weeks etc.

The outcome data in terms of discharged, death, LAMA and referred are recorded. After fish bone analysis of baseline data the QI team discussed about existing practice of O2 use and possible barriers in implementing the suggested strategy. Then how to implement the new strategy to improve the quality care is finalized. After the base line phase the training of the team members is conducted. PDSA cycle is done involving team members on 5 points like, duration of oxygen therapy to be reduced from the existing practice, given as per the specific indication, with signs of emergency, with minimum investigation prior to therapy etc, persons involved n follow up, place, duration of study and expected outcome. Training material is prepared by...
the QI team. The written material is widely circulated among other doctors and nurses for implementation. Posters regarding new protocol were displayed at several selective places to aware doctors and nursing staffs about the new strategy regarding oxygen use.

Finally, following changes are made in the system:

1. training of doctors and neonatal nurses,
2. finalizing the new protocol
3. supervised by QI team members
4. displaying the guidelines for O2 use at different places of NBU
5. Assigning the team members to collect data regarding various aspect O2 use in a predesigned case record form prepared by team members.

Post-intervention phase dealt with follow up of patients daily during the hospital stay QI team meets every week to collect feedback from all stakeholders and review each important aspects of feedback and decide to bring any changes in the system, if necessary.

Statistical Analysis

Both base line data and final data are compiled and analyzed by using statistical software, Graph pad prism version.5. The categorical data are analyzed by descriptive analysis and expressed in percentages. The comparison between base line data and final data are done by Chi-square test.

Results

Fig No.1 Distribution of O2 Therapy among Neonates

N=69 (base line data), n= 101 (final data), Data expressed in % and analysed by Chi square test, $x^2$-8.029, df-1, p<0.001.

Fig No.1 showed that there was significantly more percentage of cases received (62.5%) O2 therapy as per emergency sign in final data compared with that of baseline data (43%). In base line data more percentage of cases received O2 therapy without any emergency sign (57%).

Fig No. 3 Use of Oxygen as per Specific Sign

N=69 (base line data), n= 101 (final data), Data expressed in % and analysed by Chi square test, $x^2$-0.3205, df-1, p >0.05.

There was no significant difference between the two groups among O2 used as per specific sign. Though
there was slightly higher percentage (54%) of cases received O2 therapy as per specific indication in final data compared with baseline data.

Fig No.4 Oxygen as per Priority Sign

N=69 (base line data), n= 101(final data), Data expressed in % and analysed by Chi square test, $x^2$=8.029,df-1, p <0.001

Fig No.4 showed that in final data after intervention the O2 used as per priority sign was occurred in significantly more (64.84%) of cases than that of baseline data(43%) whereas maximum percentage of cases used not as per priority sign (57%) in baseline data.

Fig No.5 O2 Used After Minimum Investigation

N=69 (base line data), n= 101(final data), Data expressed in % and analysed by Chi square test, $x^2$=27.51,df-1, p <0.0001

Fig No.5, it was clearly observed that maximum percentage of cases received O2 therapy with minimum investigation in final data group (71.87%) which was significantly less in basal data group (35%).

Fig No.6 Duration of O2 Used

N=69 (base line data), n= 101(final data), Data expressed in % and analysed by Chi square test, $x^2$=28.90,df-5, p <0.001

Duration wis O2 uses maximum around day 7 in base data where as maximum use of O2 limited to day3.

Fig No.7 O2 Used Duration: <2 Days Vs >2 Days

N=69 (base line data), n= 101(final data), Data expressed in % and analysed by Chi square test, $x^2$=44.40, df-1, p <0.0001

Fig No.6 and fig. No.7 depicted that in final data group duration of O2 used is < 2 days (<1-2days) in significantly more number of cases (69.70%) compared with that of basal data group which was taken prior to intervention. In basal data group duration of O2 used >2 days (>2 -7 days) in more percentage (77%) of cases.

Fig. No.8 Outcome

N=69 (base line data), n= 101(final data), Data expressed in % and analysed by Chi square test, $x^2$=0.5156, df-3, p >0.05
In the above fig no.8, it was observed that there was no significant difference between the baseline data and final data at any type of outcome parameters like discharged, death, LAMA and referred.

**Discussion**

This study was conducted to implement a guideline for rational use of oxygen in sick neonates and optimise its use which reduces the use of resources as well as dangerous outcome of hyperoxia. The study result of base line data showed significant irrationality in O2 utilization in sick neonates which was not as per the WHO prescribed guide line\([6,11]\). The knowledge level of care givers like doctors and nurses was not updated regarding adverse consequences of excessive or suboptimal use of O2 therapy. Some times to satisfy the parents also they keep the patient under O2 therapy when there was no need. Oxidative stress is a serious outcome of hyperoxia due to excessive use of O2 during neonatal period and responsible for generalized tissue damage and in particular causes injury to lung, CNS, retina, red blood cells. Supplemental oxygen in new born care should be prudent to avoid changes and fluctuations in SpO\(_2\)\([3]\).

In base line data more number of cases received O2 supplementation compared to that of final data which showed unawareness of health care givers in this facility and showed wastage of resources unnecessarily. Oxygen use indicators like emergency signs, specific signs, with minimum investigations were also not as per the guide line in base line data which was changed significantly in final data. Duration of therapy >1 day to 2 days observed in final data which was significantly lesser than that of baseline data i.e ranges from 3-5days. There is no check list of oxygen supply in base line data where as in final data there was significantly reduction of amount of O2 supply\([12,15]\). Titration of O2 supply was made in final data by nasal prong at the rate of 0.5 litre/minute then supply seized without making any harm as per O2 supply guide lines. Finally from study there was significant amount of reduction of O2 consumption compared with that of baseline data. This result is similar to other Indian study\([7]\).

When at the end outcome in terms of death, discharge and LAMA were compared and showed no statistical significant difference between the base line and final data. This indicates that increasing the duration and concentration of O2 supply could not improve outcome parameters rather lead to some complications\([5,13,14,16,17]\).

An important obstacle was faced by the team members during the implementation of this QI strategy that some of the staff members were not willing rigidly to change. This was tackled by motivating them, explaining them the importance of rational use of O2 by showing different study results.

**Limitations of the Study**

The limitations of the study were shot duration study, no long term follow up of the patient for any late consequences of irrational use of O2. The specific organ level tissue injuries were not evaluated.

**Conclusion**

Oxygen saturation monitoring should occur continuously in all newborns who have respiratory distress, or commence oxygen therapy. The lowest oxygen saturation level recommended commencing oxygen therapy. Understanding the effects of O2 administration is important for the management of oxygen therapy in preterm newborn in order to prevent inadvertent cellular and tissue damage caused by hyperoxemia, in the patients requiring supplemental oxygenation. This small interventional study helped us in significantly improving the quality care regarding O2 use and prevents O2 related toxicity with available resources and manpower in resource poor setting.

**Suggestions**

O2 therapy guideline is must in every newborn units which can prevent toxicities related to over use of O2 .Periodic orientation programme/CME should be conducted among teaching faculties, SR and PG
students. Emphasis should be given for rational use of O2 during the UG and PG teaching programme. Judicious uses of oxygen are very important among preterm neonate for prevention of retinopathy of prematurity.

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