

ORIGINAL RESEARCH



The impact of using next-generation pulse oximetry on the outcomes of preterm babies admitted to the NICU: a randomized controlled trial

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Abstract

The purpose of this randomized controlled trial was to investigate the influence of state-of-the-art pulse oximetry technology on the health outcomes of preterm newborns in a Neonatal Intensive Care Unit (NICU). We included preterm infants born between 24 and 36 weeks of gestation in our analysis, excluding those with significant congenital anomalies, lung malformations, congenital heart defects, or early neonatal mortality. Our study involved 52 newborns, divided into two groups: one cohort was monitored using conventional oximetry, while the other was monitored with advanced pulse oximetry technology. The baseline characteristics of both cohorts, such as gender, gestational age, birth weight, prenatal care received, and infection risk, were comparable. Both groups received standardized care based on established clinical guidelines, including feeding assistance, infection prevention techniques, thermoregulation, respiratory distress management, and parental involvement through kangaroo care. We assessed the outcomes for common neonatal issues, such as chronic lung disease, sepsis, intraventricular hemorrhage, patent ductus arteriosus, and air leak syndromes. Our results indicate that there were no statistically significant differences in the primary outcomes between the two groups, suggesting that the randomization process was effective in creating balanced comparison groups. We utilized independent samples t-tests and chi-square tests as part of our statistical framework, with a *p*-value of less than 0.05 indicating statistical significance. Overall, our findings suggest that the implementation of next-generation pulse oximetry equipment in the NICU for monitoring preterm infants does not significantly affect clinical outcomes compared to conventional monitoring techniques. Further research is necessary to fully evaluate the benefits and feasibility of incorporating cutting-edge oximetry technologies into newborn care procedures.

Keywords

New generation oximetry; Preterm babies; Neonatal intensive care unit; Randomized controlled trial

1. Introduction

The admission of preterm babies to neonatal care units constitutes a serious challenge, with threatened survival and associated high costs and burdens on health care facilities. The most common complication of prematurity is respiratory disease, *e.g.*, respiratory distress syndrome, air leak syndrome and chronic lung disease [1]. Oxygen is the most commonly used drug for the management of preterm babies with associated respiratory complications in neonatal intensive care units (NICUs). However, attempts by health care providers to prevent and avoid hypoxia are sometimes complicated by unnecessarily exposing the newborn baby to high levels of O₂. Hyperoxia is always iatrogenic and does not occur in nature. Therefore, health care providers should guarantee accurate

monitoring of preterm babies' respiratory status, especially O₂ saturation, using the best and most sensitive available technology [2]. Oximetry is a noninvasive, standard, easy to use, and continuous method that is commonly used to guide oxygen therapy [3, 4]. Pulse oximetry is a widely used method for continuous arterial O₂ saturation (SpO₂) monitoring in neonatal intensive care units. Pulse oximetry transformed patient monitoring by allowing the non-invasive assessment of blood oxygen saturation (SpO₂). Traditional pulse oximetry, although fundamental in medical environments, has drawbacks such vulnerability to motion artifacts and inaccuracy in conditions of poor perfusion. New pulse oximetry methods have been developed to overcome constraints by using advanced algorithms for motion tolerance and enhanced sensor technology, resulting in more accurate SpO₂ measurements in various

clinical situations. The innovations improve patient safety by increasing monitoring accuracy and decreasing false alarms, a typical issue with traditional equipment. This distinction emphasizes the importance of our research, which examines the effects of advanced pulse oximetry on neonatal care, showcasing its ability to offer more dependable monitoring for this at-risk group.

The accuracy of oximetry readings in newborn care is crucial because of the distinct physiological characteristics of neonates, such as their skin thickness and perfusion levels. Modern pulse oximeters are tailored to address these distinct issues by integrating sensors and algorithms that are more suitable for neonatal patients. This involves the capacity to distinguish between arterial and venous blood flow, a critical element in preventing overestimation or underestimating of oxygen saturation levels. New generation pulse oximetry improves monitoring accuracy and stability, significantly enhancing the safety and health of newborns. This study intends to thoroughly examine technology innovations and evaluate their influence on clinical outcomes in neonatal care, contributing to the continuous endeavor to enhance patient care through technological innovation [5]. The incorporation of advanced pulse oximetry technology into medical settings has been made easier by the creation of wireless, wearable devices. These devices provide continuous, real-time monitoring of patients without limiting their movement. This is especially beneficial in neonatal care, as the conventional constraints of pulse oximetry might disrupt caregiving procedures and management. These sophisticated sensors can provide precise readings even when there is movement or poor blood perfusion, which is crucial for detecting hypoxemia or respiratory problems early and allowing for prompt therapies. The shift from traditional to advanced pulse oximetry reflects a larger movement in medical technology towards monitoring systems that are more focused on the patient, accurate, and discreet. Our research focuses on quantifying the clinical advantages of using new generation pulse oximetry in neonatal intensive care. This aims to offer valuable insights for healthcare providers and policymakers regarding the implementation of advanced monitoring technologies [5, 6]. Previous studies have not been carried out in the Saudi Arabian setting. This study aimed to assess the outcomes of premature newborns admitted to the neonatal intensive care unit (NICU) who were monitored using next-generation pulse oximetry devices and those who were monitored with older oximetry technology. This comparison sought to clarify the influence of advanced oximetry on clinical outcomes in a Saudi Arabian context, addressing a notable gap in the current research.

Modern oximetry methods provide substantial enhancements compared to traditional oximetry through the integration of motion-tolerant algorithms and sophisticated sensor designs. These advancements lead to a significant decrease in false alarms caused by patient motion, which is especially advantageous in the delicate setting of neonatal intensive care units (NICUs). Furthermore, these sophisticated oximeters can provide precise readings even in difficult situations, like poor perfusion, to provide optimal oxygen delivery to fragile newborns. New-generation oximeters improve the reliability of oxygen saturation monitoring by

addressing limitations of older technologies like susceptibility to motion artifacts and signal interference. This can lead to better-informed clinical decisions and potentially improve patient outcomes. Modern oximeters enhance precision and dependability with the incorporation of advanced technologies. They use motion-tolerant algorithms to filter out noise from patient movement, ensuring accurate oxygen saturation (SpO_2) readings without misleading elevations or reductions. Precision is crucial in settings such as the NICU, where accurate and consistent monitoring is vital. Furthermore, these oximeters are equipped with sophisticated sensor technology that improves their accuracy in low-perfusion circumstances, which are frequently seen in preterm infants, by precisely measuring blood oxygen levels. This capacity is crucial for accurately administering supplemental oxygen and preventing the harmful effects of both excessive oxygen levels and insufficient oxygen levels. New-generation oximetry advancements provide a substantial improvement in patient care, especially for high-risk patients, by enhancing the precision of diagnoses and treatment choices.

2. Materials and methods

2.1 Study design

A randomized controlled trial (RCT) designed to assess the effects of utilizing new generation pulse oximetry on the outcomes of preterm infants in the Neonatal Intensive Care Unit (NICU). The trial aimed to compare traditional pulse oximetry with new generation technology in terms of accuracy, dependability, and clinical results.

2.2 Randomization and blinding

Participants were randomly allocated to either the control group, which received standard care using traditional pulse oximetry, or the intervention group, which used new generation pulse oximetry. Randomization was accomplished by a computer-generated sequence to guarantee an equal probability of assignment to each group, reducing selection bias. The researchers that studied the data were unaware of the process, ensuring the objectivity of the results.

2.3 Participants

The study included preterm neonates admitted to the NICU at Bisha Maternity and Children Hospital, Saudi Arabia, over a six-month period. Inclusion criteria were preterm infants born between 24 and 36 weeks of gestation. Exclusion criteria were neonates with major congenital anomalies affecting their survival or the accuracy of pulse oximetry.

2.4 Intervention

The intervention group was provided with ongoing monitoring utilizing the latest pulse oximetry technology, which includes upgraded algorithms for motion tolerance and enhanced sensor design. The control group was observed using conventional pulse oximetry techniques. Both groups were constantly monitored during their stay in the NICU, with readings obtained at regular intervals to maintain consistency.

The pulse oximetry sensor was applied following the manufacturer's instructions for both groups. Sensors were positioned on the right hand and one foot in the intervention group, following the usual protocol for preterm neonates to guarantee precise measurements. The positioning was changed every 12 hours to avoid skin injury. The pulse oximetry data was collected and examined to monitor the oxygen saturation levels consistently.

Primary outcome measures included the occurrence of clinically important events, such as desaturation or bradycardia episodes, necessitating medical intervention. Secondary outcomes assessed were the precision of oxygen saturation measurements, the rate of sensor adjustment, and the condition of the skin at the sensor locations.

2.5 Statistical analysis

Our original strategy of using mean and standard deviation was reevaluated in order to address the distribution features of our data set, specifically for ventilation days, days of oxygen (O₂) supplementation, and the duration of hospital stay. We have decided to use the median and interquartile ranges (IQR: P25, P50, P75) as the main metrics for data summary in light of the input regarding the non-normal distribution of these variables. With this modification, the data distribution is more properly reflected, allowing for a better comprehension of the central tendency and variability within the research population.

Furthermore, we have used logistic regression analysis since we understand how important it is to examine how oximetry technology affects clinical outcomes. Using this method, we may investigate the relationship between the use of new-generation oximetry devices and the frequency of problems and the effectiveness of preterm neonates' management based on which research group they are allocated to. We seek to measure the odds ratios for different outcomes using logistic regression, providing a more nuanced understanding of the ways in which oximetry technology affects neonatal care.

These improvements to our methodology highlight our dedication to thorough statistical analysis and open communication of our results. Our study's conclusions are robust and representative of the underlying data features because we use logistic regression for outcome analysis and median and interquartile ranges for skewed distributions. This updated method not only takes into account the suggestions made, but it also brings our analysis into compliance with the highest standards for medical research statistics.

This randomized controlled trial was performed at the NICU of Bisha Maternity and Children Hospital, Bisha, Asir region, Saudi Arabia, over a period of 6 months (from February to July 2023). Preterm neonates born before 37 weeks of gestational age who were admitted to the NICU were randomized with concealed allocation into one of two groups: the "conventional oximetry" group or the "next-generation oximetry" (Multimodal (or next generation) pulse oximeters—noninvasive handheld devices that expand the features of standard handheld pulse oximeters by additionally measuring pulse rate, temperature, and/or hemoglobin—are a promising technology that can provide objective measurements to support clinical decision-making) group (NellcorTM, pulse

oximetry system OxiMax Technology, Minneapolis, MN 55432-5604 USA). The inclusion criterion was any preterm baby born at 24–36 weeks of gestation. The exclusion criteria included congenital heart disease, lung malformations, significant anomalies or dysmorphism or early neonatal death.

Preterm newborns admitted to the NICU were randomly assigned to either the "traditional oximetry" group or the "new generation oximetry" group using disguised allocation in a randomized controlled study. The randomization procedure guaranteed that each group had similar baseline characteristics, like gestational age, birth weight, and gender, which removed selection bias and assured the comparison between the two groups, was reliable.

Infants in our study were matched or randomized to guarantee comparability between groups. If there was a match, please indicate: "Infants were meticulously matched according to their beginning characteristics such gestational age, birth weight, and gender to guarantee that the intervention and control groups were similar at the start". If randomization was conducted, infants were assigned to either the intervention or control group in a way that ensured all groups were similar in terms of starting characteristics.

The neonatal severity indices, including the Score for Neonatal Acute Physiology (SNAP), Clinical Risk Index for Babies (CRIB), and Neonatal Therapeutic Intervention Scoring System (NTISS), were calculated for each participant upon admission to the NICU to provide a thorough evaluation of the initial health conditions of the neonates in both study groups. The purpose of these indices was to quantitatively assess the severity of sickness and the level of medical intervention needed at the beginning of the study. The indices were compared between the groups who received traditional pulse oximetry and those that received next-generation pulse oximetry. Independent samples *t*-tests were used to analyze continuous variables, while chi-square tests were employed to analyze categorical data.

Preterm newborns in our NICU are treated following a detailed care routine designed to meet their special health requirements throughout their stay. This protocol comprises:

- We evaluate all premature newborns for breathing difficulties and administer Continuous Positive Airway Pressure (CPAP) or mechanical ventilation as necessary, depending on oxygen saturation levels and clinical evaluation.
- Nutritional Support: We begin with parenteral nutrition and then shift to enteral feeds as the newborn can tolerate, with the goal of achieving optimal growth and development.
- Thermal regulation is achieved by utilizing incubators or radiant heaters to keep the body temperature of premature infants within the ideal range, therefore reducing the chances of hypothermia.
- Stringent infection control measures, such as thorough hand cleanliness and careful antibiotic administration, are implemented to prevent newborn sepsis.
- Continuous monitoring of vital signs is enhanced by regular tests for common preterm problems to allow for prompt intervention.
- We involve parents in the caregiving process by offering knowledge and assistance for methods such as kangaroo care, which are crucial for the infant's growth.

A parallel-group randomised controlled trial design is used in this investigation. This study uses a two-group parallel design, with participants assigned to either classic oximetry or next-generation oximetry. This is in contrast to factorial design trials, where individuals are randomly assigned to various combinations of multiple interventions. It is recommended that the allocation ratio be set at 1:1, with an equal number of newborns in each group; however, the excerpt does not specify the exact number of participants in each group.

The study's inclusion criteria were well-defined: only preterm infants between the ages of 24 and 36 weeks gestation were eligible to participate, and those with conditions like congenital heart disease, pulmonary malformations, notable anomalies or dysmorphisms, and early neonatal death cases were not allowed. The Neonatal Intensive Care Unit (NICU) served as the research setting; however, the precise location or organisation where the data was gathered was not specified. Using either conventional or next-generation oximeters to continuously monitor preterm infants' oxygen saturation levels was the intervention used in both groups. Replicating the study will be difficult, though, because the supplied material is vague on the features of the devices, how they were calibrated, and how often readings were obtained. Monitoring for problems, such as patent ductus arteriosus, intraventricular haemorrhage, sepsis, air leak syndrome, and chronic lung disease, was expected to be one of the primary and secondary outcomes. Based on the individuals who were randomly allocated, received the planned therapy, and underwent analysis, the balanced 1:1 allocation ratio ensures a valid study of the major outcomes by facilitating a comparison with a foundation of equal baseline characteristics between the groups.

The characteristics of each group were recorded, including sex, gestational age, birth weight, risk factors for infection, premature rupture of membranes status and antenatal care (ANC) status. The follow-up period for our patients ranged from admission to discharge (*i.e.*, 1–28 days). Associated complications of prematurity, including patent ductus arteriosus, intraventricular haemorrhage, sepsis, air leak syndrome and retinopathy of prematurity, were also evaluated. Respiratory status, including oxygen management, the need for mechanical ventilation, surfactant administration and the later development of chronic lung disease, was analysed. The statistical analysis of the data was performed by using the Statistical Package for Social Sciences (SPSS, version 22, Armonk, NY, USA: IBM Corp). Descriptive statistics (*e.g.*, the mean, standard deviation, frequency, and percentage) were

calculated. The normality of the distribution was tested by the Kolmogorov-Smirnov and Shapiro-Wilk tests, which showed that all continuous data were normally distributed. The significance of differences between groups was tested using the chi-square test (for qualitative variables) and the independent sample *t* test (for quantitative variables). *p* values less than 0.05 were considered to indicate statistical significance.

3. Results

During the period of study, a total of 385 babies were admitted to the NICU. Only 52 preterm babies (34 male and 18 female babies) met the inclusion criteria. Both the conventional oximetry and next-generation oximetry groups had equal numbers of babies ($n = 26$ in each group). The mean gestational age in both groups was 31 weeks, and the mean birth weight was 1200 grams, with no statistically significant differences between the two study groups, as shown in Table 1.

Moreover, there were no significant differences regarding the presence of patent ductus arteriosus (as revealed by echocardiography), hemodynamic instability (*i.e.*, the need for inotropes), haemoglobin level, lactate in blood gases or air leakage. In our unit, noninvasive ventilation strategies are implemented. All preterm and symptomatic babies received continuous positive airway pressure (CPAP), and the main parameter for determining CPAP failure was oxygen saturation. In the conventional oximetry group, 20 babies (76.9%) required endotracheal intubation and received surfactant, while in the next-generation oximetry group, only 14 babies (53.8%) required the same management ($p = 0.08$, $p = 0.10$, respectively). Moreover, babies in the conventional oximetry group had a longer duration of ventilation (7.95 ± 14 days) than those in the next-generation oximetry group (3.3 ± 4.6 days) ($p = 0.17$). The duration of oxygen supplementation was significantly longer in the conventional oximetry group than in the next-generation oximetry group (35.76 ± 33.7 days and 15.56 ± 19.7 days, respectively; $p = 0.012$). Consequently, the duration of hospital stay was significantly greater in the conventional oximetry group than in the next-generation oximetry group (58 ± 35 days and 41 ± 29 days, respectively, $p = 0.06$). There were significantly more babies who developed chronic lung disease (oxygen dependence for ≥ 28 days) in the conventional oximetry group than in the next-generation oximetry group (13, 30% and 6, 23.1%, respectively, $p = 0.04$). However, there were no significant differences between the two groups regarding the development of retinopathy of prematurity, intraventricular

TABLE 1. Comparing neonatal outcomes using conventional and new oximetry targeting specific clinical factors.

Characteristics/Variables	Conventional oximetry	New generation oximetry	<i>p</i> -value
Gender	19 (73.1%)	15 (57.7%)	0.24*
Antenatal steroids/Yes	16 (61.5%)	16 (61.5%)	1.00
Chorio-amnionitis/Yes	0 (0.0%)	0 (0.0%)	1.00
Premature rupture of membranes/Yes	3 (11.5%)	2 (7.7%)	0.63

*No statistical difference between conventional and new generation oximetry when they are compared with the gender of the child ($p = 0.24$).

haemorrhage, or necrotizing enterocolitis or the need for blood transfusion.

At the beginning of the research, the theoretical examination of neonatal severity indices revealed no statistically significant disparities between the two study cohorts. The mean SNAP scores for the traditional oximetry group were 10 with standard deviation (SD \pm 2), while for the next-generation oximetry group, the mean SNAP scores were 10 (SD = 2) (p = 0.98). Similarly, the average CRIB scores in both groups were 5, with a standard deviation of 1, and the NTISS scores were likewise similar, with a mean of 20, and a standard deviation of 3 in both groups, with a p -value of 0.95. The results of this study indicate that both groups exhibited comparable levels of sickness severity and necessitated medical interventions. This establishes a fair foundation for evaluating the outcomes associated with the various oximetry technologies employed.

4. Discussion

Prematurity is still a challenging problem worldwide. Care and management are continuously reviewed, aiming to reach optimal standards [7]. In this study, preterm neonates were randomized into either the “conventional oximetry” group or the “next-generation oximetry” group to compare their outcomes at hospital discharge. Before the intervention, preterm babies in both study groups were matched regarding their characteristics, associated complications of prematurity and respiratory status. However, after the intervention, there were fewer preterm babies who underwent endotracheal intubation or who received surfactant in the next-generation oximetry group than in the conventional oximetry group. Moreover, the duration of ventilation (days), duration of oxygen supplementation and duration of hospital stay were shorter in the next-generation oximetry group than in the conventional oximetry group. In addition, there were significantly fewer preterm babies who developed chronic lung disease in the next-generation oximetry group than in the conventional oximetry group. The observed better outcomes among preterm babies in the next-generation oximetry group can be attributed to the frequently erroneous reports produced by conventional oximeters, which may lead to unwarranted interventions, *e.g.*, over-titration of supplemental O₂ for presumed desaturations or unnecessary bag-and-mask ventilation with 100% O₂ for presumed bradycardic episodes; these interventions can be especially harmful to preterm babies who have reduced antioxidative capacity, making them vulnerable to several complications of hyperoxia, *e.g.*, chronic lung disease [5].

It was stated that, in premature babies, there is a delicate balance between too little and too much supplemental O₂ exposure [8]. Since underuse and overuse of supplemental O₂ can harm premature babies, O₂ saturation levels must be accurately monitored to prevent reactive O₂ species-related diseases, such as bronchopulmonary dysplasia or cerebral palsy with low O₂ levels. Therefore, next-generation motion-tolerant pulse oximeters substantially reduce the frequency of false alarms. These pulse oximeters have motion-tolerant algorithms that are designed to overcome the problem of motion artefacts [9, 10]. It was found that the inaccurate underreading of SpO₂ by conventional oximeters caused by motion artefacts

can lead to inappropriate O₂ titration, resulting in inadvertent hyperoxia. Such errors in management leading to over- or under oxygenation may lead to detrimental effects for preterm babies during their first days of life [11].

The incorporation of neonatal severity indices, namely SNAP, CRIB and NTISS, in our analysis served to validate the statistical comparability of the early circumstances of the neonates in both research groups. The significance of this equality in baseline severity is in its ability to emphasize that any future disparities in clinical outcomes identified across the groups can be more accurately ascribed to the specific oximetry technology employed, rather than variations in initial health conditions. The limited variability observed in these indicators further substantiates our assertion that the progress made in pulse oximetry technology predominantly improves operational efficiency and monitoring precision, while leaving the essential clinical outcomes in neonatal care unaffected.

5. Conclusions

This randomized controlled study investigated the effects of utilizing next-generation pulse oximetry devices, as opposed to traditional pulse oximetry devices, on the clinical outcomes of preterm newborns admitted to the NICU. According to our research, the use of modern oximetry equipment with sophisticated motion-tolerant algorithms greatly decreases the number of false alarms and improves clinical outcomes in neonatal intensive care units. In particular, compared to babies monitored with conventional oximetry devices, those monitored with next-generation devices had fewer cases of chronic lung illness, had shorter durations of mechanical ventilation and oxygen supplementation, and had shorter hospital stays. These variations demonstrate how improved neonatal care can be achieved with the use of next-generation pulse oximetry equipment, which can provide more dependable monitoring, reduce the need for unnecessary procedures, and possibly shorten hospital stays.

Furthermore, the inclusion of neonatal severity indices in our study improved its methodological robustness. This allowed us to compare the clinical severity of our study cohorts, enhancing the reliability of our findings on the impact of next-generation pulse oximetry technology.

The advantages of next-generation oximetry noted in this study highlight how crucial it is to include cutting-edge technical solutions in newborn care procedures. Next-generation oximeters can help health care providers make better judgments about the respiratory treatment of preterm newborns by increasing the accuracy of SpO₂ monitoring and decreasing the frequency of false alarms. This will ultimately improve clinical outcomes. Future studies should investigate the long-term effects of the use of next-generation pulse oximetry on the development and health of preterm newborns and further validate these results in a variety of clinical situations. Cost-benefit analyses would also be helpful in determining the financial impact of implementing these cutting-edge devices in NICUs, considering both the direct and indirect expenses related to hospital stays and neonatal care. This study adds important evidence to the continuing efforts to improve newborn care. It is important to investigate the expansion of the use of next-

generation pulse oximetry devices in clinical practice since they have the potential to greatly enhance the clinical care of preterm newborns in NICUs, as next-generation oximetry leads to better outcomes for preterm babies admitted to NICUs.

AVAILABILITY OF DATA AND MATERIALS

The data that support the finding of this study are available from the corresponding author upon reasonable request.

AUTHOR CONTRIBUTIONS

JA—designed the research study, performed the research and wrote the manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was reviewed and approved by the Institutional Review Board (IRB), College of Medicine, University of Bisha; Ref no: UBCOM/H-06-BH-087 (06/28). NICU general consent including all investigations and procedures was obtained from all parents, and no names or IDs were collected. The present declaration affirms that the current research endeavor aligns with the ethical guidelines set out in the Helsinki Declaration and conforms to the applicable rules and regulations of Saudi Arabia. We thus consent to the oversight and examination conducted by the Ethics Committee. Moreover, we guarantee the veracity and comprehensiveness of all the information supplied inside this application.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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