An-Najah National University

Faculty of Graduate Studies

COMPARING THE EFFECTS OF VOLUME-TARGETED VENTILATION MODE AND TRADITIONAL PRESSURE-LIMITED VENTILATION MODE ON THE CLINICAL OUTCOMES OF PREMATURE BABIES WITH RESPIRATORY DISTRESS SYNDROME. A CONTROLLED RANDOMIZED STUDY

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This Thesis is submitted in Partial Fulfilment of the Requirements for the Degree of Master of Critical Care Nursing, Faculty of Graduate Studies, An-Najah National University, Nablus - Palestine.

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Dedication

I dedicate this work,

To my dear father and mother who instilled in me the love of the homeland and knowledge-seeking.

To my husband and my children (Karmel and Karam) for their love.

To my brothers and sisters.

My special thanks to my mother-in-law and all my family and friends for taking such keen interest in completing this thesis successfully,

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Now as my thesis has been completed,

First, I would like to express my gratitude to Almighty Allah to enabling me to complete this research.

I would like to thank everyone who supported the research from the very beginning.

I am also thankful to the people who have made the essential information accessible to me.

My appreciation especially goes to my supervisor (Dr. Aidah Alkaissi).

Finally, I would like to deliver my sincere thanks to my colleagues and friends.

Declaration

I, the undersigned, declare that I submitted the thesis entitled:

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I declare that the work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

Student's Name: _____

Signature: _____

Date: _____

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COMPARING THE EFFECTS OF VOLUME-TARGETED VENTILATION MODE AND TRADITIONAL PRESSURE-LIMITED VENTILATION MODE ON THE CLINICAL OUTCOMES OF PREMATURE BABIES WITH RESPIRATORY DISTRESS SYNDROME. A CONTROLLED RANDOMIZED STUDY

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Abstract

Respiratory distress syndrome (RDS) occurs when the lungs of a premature infant are not fully developed and lack the surfactant needed to keep the air sacs open. Different modes of ventilation have evolved to decrease the lung damage of the premature infant and control the amount of air that enters the lungs with each inflation. The most commonly used modes are the traditional Pressure-Limited Ventilation (PLV) and the new Volume Targeted Pressure (VTV).

The study aims to compare the effect of VTV and PLV on the clinical outcome (BP, RR, HR, SaO2, Tidal volumes and FiO2), length of intubation duration, Oxygen therapy duration and the consequent complications of the premature babies with RDS in Jenin governmental hospital.

The study used a randomised controlled trial design. 80 premature babies made up the sample, of which 40 were randomly assigned to the experimental group (VTV) and 40 to the control group (PVL). The data was gathered using the patient data sheet.

The total number of male participants was 42 (27 VTV and 15 PLV), while the total number of females was 38 (13 VTV and 25 PLV). The gestational age ranged from 29 to 36 weeks. In this study 32.5 % of all the participants were in the age group between 0-7 days, while 11.3% were in the age group from 22-24 days. The highest birth weight group was from 1.51 to 2.5 Kg (46.3%), while the lowest was more than 3.5 kg (1.3%). The weight of the largest number of the participants from the two groups ranged between 1.51 to 2.5 kg, while those weighting more than 3.5 kg were the lowest number

of the participants. A total of 37.5% of participants delivered by normal vaginal delivery, while 62.5% of participants delivered by caesarean section. The mean of Spo2 in VTV (Mean=97.7) at the total 24 hours was significantly higher than the mean in PLV (Mean=95.86). There are significant differences between VTV group and PLV group in the FiO2 at the sixth, seventh and eighth 3 hours. The number of dead patients in the PLV 8(20%) was higher than in the VTV 3(7.5%), P= 0.105. However, there was no statistical significance in difference, but clinically it was relevant. The study could not identify an increase in any adverse outcomes associated with the use of VTV compared with PLV.

VTV mode produced improved oxygen saturation values for SPO2, and FiO2 in comparison to PLV mode, The results showed that the number of dead patients in the PLV group higher than in the VTV. However, there was no statistical significance in difference, but clinically it was relevant. There was no evidence of an increase in any unfavourable outcomes associated with the use of VTV in comparison to PLV.

Keywords: VTV, PLV, Premature, RDS, Palestine.

Chapter One

Introduction and Theoretical Background

1.1 Introduction

Overview

Neonates who are born alive earlier than the 37th week of pregnancy are considered premature; The World Health Organization (WHO) report in 2018, it was estimates that 15 million infants are born prematurely each year; This applies to more than one out of every 10 babies; A million or more children every year die because of complications from premature birth; Many survivors live with disabilities throughout their lifetimes, including difficulties with their hearing, vision, and learning; Around the world, prematurity is the leading cause of mortality amongst infants below the age of five; Additionally, premature birth ratios are rising in almost all nations (WHO, 2018). Based on gestational age, premature birth can be classified into three categories: moderate to late premature (from 32 to 37 weeks), very premature (from 28 to 32 weeks), and extremely premature (less than 28 weeks) (WHO, 2018).

The major diagnosis of premature newborns hospitalized to NICU is respiratory distress syndrome (RDS), accounting for almost 100% of extremely low birth weight (ELBW) newborns and about 29 percent of late premature newborns (Stoll et al., 2010).

RDS is diagnosed when a baby's lungs are not fully developed and cannot provide enough oxygen, causing breathing difficulties; Significant progress has been accomplished over the past 50 years in our understanding of newborn pulmonary physiology, the impact of respiratory distress on other bodily systems, and the long-term consequences of current respiratory modalities, such as mechanical ventilation (MV) and supplemental oxygen use (Goldsmith & Karotkin, 2011). With a better knowledge of the long-term consequences of newborn respiratory problems, the scientific data has directed physicians in delivery room management, identification of respiratory distress, and mechanical ventilation systems (Lozano & Newnam, 2016).

Both term and premature neonates can have RDS, which is considered a prevalent reason of respiratory failure among newborns. It is caused by a combination of issues such as structural immaturity of the lungs, as well as surfactant deficiency or inactivation (Wambach & Hamvas 2014).

RDS is diagnosed using a combination of clinical evaluation, blood gas analysis, and radiographic findings. RDS usually begins during the time of initial few hours of life and reaches its peak point of severity within 48 hours. Without any early clinical sequelae, many premature infants recover from RDS. Furthermore, the data indicates that during the first few ventilated breath, lung injury or damage may occur. Also, premature neonates who are ventilated for several days or weeks may develop complications and lung injury due to one or more factors, such as oxygen toxicity, long period of ventilation, and infection, on a background of structural lung immaturity (Chitty & Sinha, 2015).

Mechanical ventilation is one of the most prevalent methods used in the management and treatment of premature infants with RDS in NICU, but due to a lack of comprehensive scientific data, it is an area where technological complexity overlaps individual preferences (Al Hazzani et al., 2017).

Synchronized Intermittent Mandatory Ventilation (SIMV) provides a predetermined number of breaths per minute (BPM), but the breaths are started by identifying neonates' spontaneous attempts at breathing and synchronizing the delivery of the ventilator breaths to meet the neonate's own breaths. In addition, premature newborns with SIMV may breathe more spontaneously in between ventilator-assisted breaths (Petty, 2013).

Neonatal ventilators are usually used in a pressure limited mode, in which a variable amount of air enters the lungs as a consequence of the pressure ventilation (With pressure ventilation, a specified gas pressure is provided to the patient and maintained during the ventilation phase). New volume-targeted ventilation (VTV) techniques have been developed with the aim of avoiding lung injury by adjusting the quantity of air

entering the lungs with each inflation, (Volume ventilation provides a specific volume of air with each breath known as a tidal volume) (Klingenberg et al., 2017).

Evidence indicated that the current use of the volume target ventilation (VTV) mode showed a decrease in the bronchopulmonary dysplasia and death rates among the premature infants (Hodgson et al., 2020). Further, the duration of mechanical ventilation, pneumothorax, grade three to four intraventricular haemorrhage (IVH), and hypocarbia, were all reduced in the premature infants who were ventilated by VTV mode in comparison to PLV (Peng et al., 2013). Therefore, this study aims to compare the effect of VTV and PLV on the clinical outcome (BP, RR, HR, SaO2, tidal volumes and FiO2), length of intubation duration, oxygen therapy duration and the consequent complications of the premature babies with RDS in Jenin governmental hospital.

Research questions

- What are the general characteristics of premature babies including (Gender, gestational age, current age, age at intubation, type of delivery, birth weight and current weight) for neonates either on VTV or PLV?
- Does the VTV have a different clinical outcome including (BP, RR, HR, SPO2, tidal volumes, and FiO2) when compared with PLV in premature babies with RDS?
- What is the length of management related to (length of intubation, and oxygen therapy duration).
- Is there any complication resulting from VTV or PLV?

Problem statement

Over the last decade, RDS is considered the most prevalence respiratory disorder in premature babies (Rodriguez, 2003). Premature infants may require assistance in breathing. With growing immaturity, the chance of lung problems rises. The use of mechanical ventilator can save the lives of certain newborns; nevertheless, ventilators can harm the immature infant's lungs. Mechanical ventilators have traditionally been utilized for premature newborns in the PLV mode of ventilation, which leads to the entry of a varying amount of air into the lungs. New VTV techniques were created with

the goal of reducing lung damage by regulating the quantity of air that enters the lungs with each inflation (Klingenberg et al., 2017).

For premature newborns, RDS remains a significant issue, but treatment has developed over the years, leading to increased survival for premature babies but with unacceptable rates (Sweet et al., 2019). Recent research on the preterm infants with RDS investigated the optimal mechanical ventilation methods for newborns (Solberg et al., 2018). It revealed that premature newborns who were ventilated utilizing VTV mode showed decreased rates of mortality, pneumothorax, hypocarbia, bronchopulmonary dysplasia (BPD), severe cranial ultrasonography abnormalities, and ventilation duration compared to those who were ventilated using PLV modes (Klingenberg et al., 2017).

In Palestine, the overall prevalence of RDS in premature infants was 33.3% (Ali et al., 2020). Also, only PLV is implemented while the VTV is not used in the NICU. In addition, there are no studies conducted to compare between the effects of VTV mode and traditional PLV mode on premature newborns with RDS in Palestine.

In conclusion, while there is some evidence suggesting that volume-targeted ventilation mode may be more beneficial for premature babies with RDS than traditional pressure-limited ventilation mode, more research is needed to fully understand the potential effects of these ventilation modes on this patient population. In addition, there is a need for a comparative study that directly compares the effects of these two ventilation modes on premature babies with RDS. Therefore, the researcher decided to focus on this topic.

Significant of the study

Currently, we need to switch from traditional pressure control modes to volume control modes because most premature newborns in the NICU develop pneumothorax and other complications. According to studies, babies who were ventilated utilizing VTV mode were greater likelihood to live without lung injury, they required less ventilator support for a littler period of time and were less likelihood to have a pneumothorax. They

showed additional consistent levels of co2 in the blood and less anomalies in the brain (Klingenberg et al., 2017).

This study is very significant research because it attempts to compare the outcome of each ventilator mode and the duration of its use to control and manage the respiration of the premature infants.

This might increase the nurse's awareness about modes of ventilation setting for premature babies in NICU. Thus, it might help in promoting the health outcome for premature babies in NICU.

Moreover, this study is expected to support the use of the effective mode of ventilation depending on the outcome of the premature infants so as to improve their health which will return a benefit for the family and the hospital in general.

Objectives

General objective

The aim of the study is to compare the effect of VTV and PLV on the clinical outcome (BP, RR, HR, SaO2, Tidal volumes and FiO2), length of intubation duration, Oxygen therapy duration and the consequent complications of the premature babies with RDS in Jenin governmental hospital.

Specific objective

- To determine the general characteristics (Gender, gestational age, current age, age at intubation, type of delivery, birth weight and current weight) for neonates either on VTV or PLV.
- To ascertain whether the VTV have a different clinical outcome including (BP, RR, HR, SPO2, tidal volumes, and FiO2) when compared with PLV in premature babies with RDS.
- To identify the length of management related to (length of intubation, and oxygen therapy duration).
- To assess the premature babies for any complications.

Research hypothesis

- There is no significant difference at a level of 0.05 related to general characteristics (Gender, gestational age, current age, age at intubation, type of delivery, birth weight and current weight) between VTV and PLV in premature babies with RDS.
- There is no significant difference at a level of 0.05 related to clinical outcome including (BP, RR, HR, SPO2, tidal volumes, and FiO2) between VTV and PLV in premature babies with RDS.
- There is no significant difference at a level of 0.05 related to length of management (length of intubation, and oxygen therapy duration) between VTV and PLV in premature babies with RDS.
- There is no significant difference between VTV and PLV at a level of 0.05 related to occurrence of any complications in premature babies with RDS.

Definition of related terms

Volume-targeted ventilation

"It is a mode that requires the clinician to set the peak flow rate, flow pattern, tidal volume, respiratory rate, positive end-expiratory pressure (applied PEEP, also known as extrinsic PEEP), and fraction of inspired oxygen (FiO2). Inspiration ends once the inspiratory time set has elapsed. The inspiratory time and inspiratory to expiratory (I: E) ratio are determined by the peak inspiratory flow rate. Increasing the peak inspiratory flow rate will decrease inspiratory time, increase expiratory time, and decrease the I:E ratio" (Hyzy & Jia, 2021).

Pressure-limited ventilation

"It is a modality utilized in patients with an indwelling endotracheal tube or tracheostomy tube that affords the practitioner the ability to ventilate a patient with a maximal peak pressure. In contrast to volume-controlled ventilation, pressure-control involves the selection of an inspiratory pressure instead of a tidal volume target. The setting of an inspiratory pressure, as well as an associated positive end-expiratory pressure (PEEP), will allow a provider to control the peak pressure, thereby protecting from barotrauma" (Messina & Olarewaju, 2021).

Premature babies

"Are those that are born alive before the 37th week of pregnancy. Premature birth can be divided into three groups based on gestational age: extreme premature (less than 28 weeks), very premature (28 to 32 weeks), and moderate to late premature (32 to 37 weeks)" (WHO, 2018).

Neonatal respiratory distress syndrome (RDS)

"It is a general term used to describe any neonatal condition that leads to a progressive state of hypoventilation and/or hypoxia. This condition commonly presents with 1or more physical symptoms that include tachypnea, grunting, retractions, nasal flaring, and cyanosis. It is a specific term that refers to a surfactant-deficient state that is most linked to prematurity. Pulmonary surfactant deficiency secondary to inactivation may also present as RDS in the term infant, although less likely" (Lozano & Newnam, 2016).

1.2 Theoretical Background

Neonatal respiratory distress syndrome (RDS)

Recently, the majority of NICUs admissions are due to prematurity. Infants are at risk for several newborn complications (such as intellectual and motor delays, respiratory distress syndrome (RDS), hyperbilirubinemia) due to the immaturity of most organ systems (Faan et al., 2016).

As for RDS, it is known that insufficient synthesis of surfactant, a mixture made up of apoproteins and phospholipids that adhere to the interior surfaces of alveoli, enhances the lung's capacity to remain inflated throughout exhalation and lowers the surface tension of surfaces. This means that respiratory difficulties develops when there is insufficient synthesis of this substance. Though primarily seen in the newborns, RDS is also seen in more mature infants. Precipitating factors include prematurity, cesarean delivery without labor, maternal diabetes, and multiple gestations (Potts & Mandleco, 2011). Therefore, respiratory distress is the term used to describe respiratory dysfunction in newborns and is primarily an illness associated with a delay in the maturation of the lungs. Most frequently, the names hyaline membrane disease and respiratory distress syndrome are used to describe this severe lung disorder, which is not

only the leading cause of infant mortality but also carries the greatest risk of long-term neurologic and respiratory complications (Faan et al., 2016).

Risk factors for RDS

The overall risk factors of neonatal RDS includes Prematurity, Hypovolemia, Hypothermia, Cold stress, Acidosis, Multiple births, Maternal diabetes, Elective CS without labor, and Genetic disorders of surfactant production (e.g., surfactant protein B mutation) (Hassan, 2018).

Pathophysiology

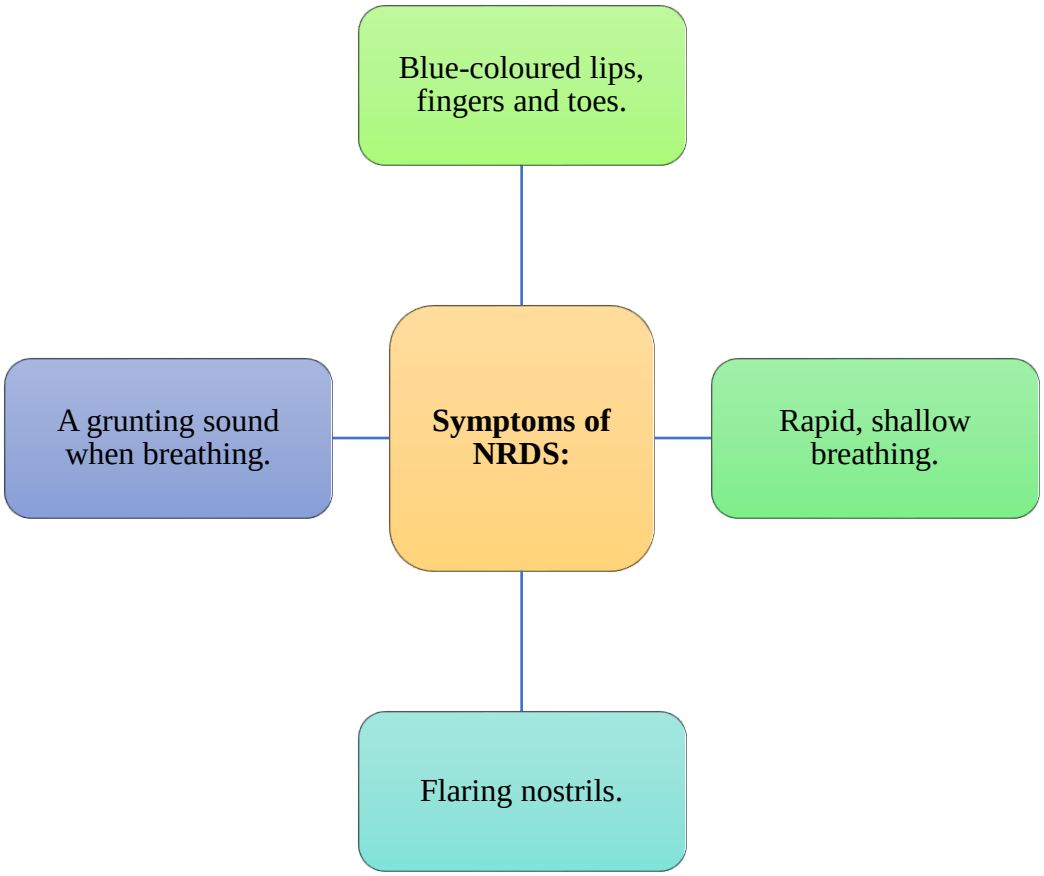
This disorder is caused by surfactant deficiency which typically begins in production at 24–28 weeks of gestation and but after 35 wk the mature levels of pulmonary surfactant are usually present. Surfactant is a lipoprotein produced by Type II cells or Type II pneumocytes. Surfactant decreases surface tension in the alveolus during expiration, allowing the alveolus to remain partly expanded after expiration & thus requiring less negative pressure and exertion to take next breath. Microscopically, a surfactant deficient lung is distinguished by collapsed airspaces and, in time, hyaline (a glass-like appearance) membranes which are lining or filling the alveoli and blocking gas exchange (Hassan, 2018). The small alveoli collapse with each breath, when there is not adequate surfactant, As the alveoli collapses, damaged cells collect in the airways. They also have an impact on respiration. The newborn needs to act harder and harder to breathe seeking to reinflate the collapse in the airways. The newborn breathes less oxygen as her or his lung function gets worse. In the blood, more carbon dioxide accumulates. This can cause the blood's acid level to rise (acidosis). Other bodily organs may be impacted by this condition. With no treatment, the newborn eventually gives up after becoming exhausted from attempting to breathe. Instead, a ventilator must do the task of breathing (Stanford Medicine Children’s Health, 2020).

Signs and Symptoms of RDS

The signs and symptoms of RDS includes tachypnea; audible grunting; nasal flaring; and subcostal, intercostal, and sternal retractions. Auscultation will show poor lung aeration despite significant respiratory effort. Symptoms can worsen to the point where supplemental oxygen or mechanical ventilation may be required (Potts & Mandleco, 2011).

Figure 1

Common symptoms of newborn respiratory distress syndrome (NRDS)



Note: National Health Service, 2021.

Diagnosis of RDS

The newborn is diagnosed with RDS depending on the health history, physical examination, lab findings, and chest X-rays. The diagnosis is suspected when the infant is born prematurely and having the clinical manifestation that mentioned above. Although chest radiography in babies with RDS might vary, it often reveals fibrosis, atelectasis, and alveolar hyperinflation. Also, signs of metabolic acidosis hypercapnia, and hypoxemia are frequently found in laboratory findings. RDS is diagnosed only after ruling out other diseases, such as patent ductus arteriosus, sepsis, and pneumonia (Potts & Mandleco, 2011).

Treatment of RDS

According to Ricci and Kyle (2009), intensive respiratory care, often with mechanical ventilation, is the main emphasis of management of RDS. The treatment of RDS includes urgent delivery of sufficient oxygenation, ventilation, supportive care, and procedures necessary for any premature newborn, in addition to those introduced to avoid additional complications related to premature birth. The supportive interventions most important to a positive outcome are to: provide acceptable oxygenation and ventilation; prevent hypotension; preserve acid–base balance; maintain suitable tissue perfusion and oxygenation; maintain sufficient hydration and electrolyte status; and maintain a neutral thermal environment (Perry et al., 2018).

Also, Surfactant replacement therapy is considered a treatment for RDS in premature infants; It is a substance that helps reduce the surface tension in the lungs and helps keep the air sacs (alveoli) from collapsing; In premature infants, RDS is a common condition caused by the immaturity of their lungs, which can result in difficulty breathing and a lack of oxygen; The use of surfactant in the treatment of RDS in premature infants has been shown to be highly effective; Surfactant therapy involves administering a dose of surfactant directly into the infant's lungs through a breathing tube; The surfactant helps to stabilize the alveoli and prevent them from collapsing during exhalation, which in turn improves the infant's ability to breathe and reduces the risk of complications such as pneumonia and bronchopulmonary dysplasia; There are different types of surfactants available, including natural surfactants derived from animal sources and synthetic surfactants that are made in a laboratory; The type of surfactant used may vary depending on the severity of the infant's RDS and other factors, such as their gestational age; Surfactant therapy is typically administered soon after birth, and in some cases may be given prophylactically to infants who are at high risk for developing RDS; The procedure is generally considered safe, although there may be some risks associated with the use of surfactant, such as infection or lung injury; Overall, the use of surfactant in the treatment of RDS in premature infants has been shown to improve outcomes and reduce the risk of complications; It is an important part

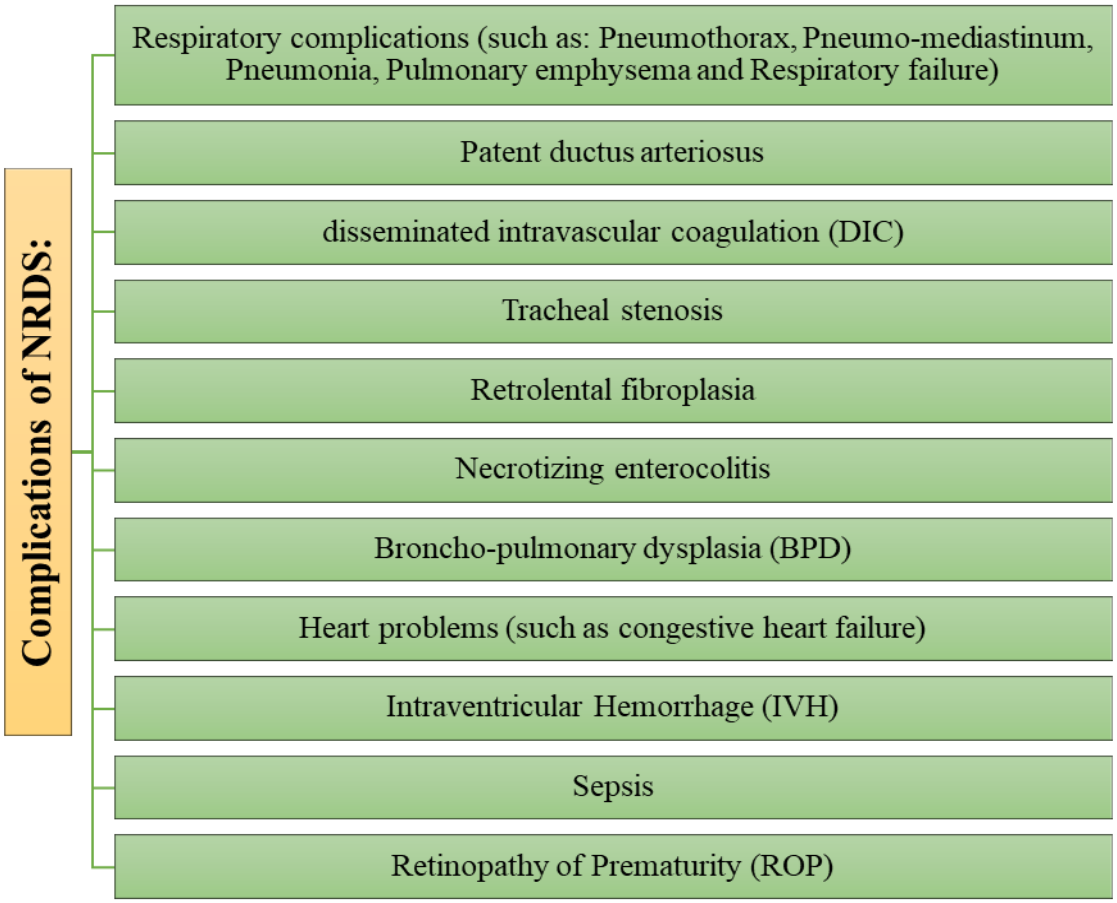
of neonatal care and is commonly used in neonatal intensive care units (NICUs) around the world (Bohlin et al., 2007; Jobe, A. H., 2011; Sweet et al., 2019).

Complications of RDS

Complications of RDS includes (1) complications related to respiratory therapy (such as: Pneumothorax, Pneumo-mediastinum, Pneumonia, Pulmonary emphysema and Respiratory failure); (2) Patent ductus arteriosus; (3) disseminated intravascular coagulation (DIC) "due to consumption of clotting factors"; (4) Tracheal stenosis; (5) Retrolental fibroplasia; (6) Necrotizing enterocolitis; (7) Broncho-pulmonary dysplasia (BPD); (8) Heart problems (such as congestive heart failure); (9) Intraventricular Hemorrhage (IVH); (10) Sepsis; and (11) Retinopathy of Prematurity (ROP) (Hassan, 2018).

Figure 2

Common complications of newborn respiratory distress syndrome (NRDS)



Note: National Health Service, 2021.

Traditional pressure-limited ventilation mode

Also known as “Pressure-Control Mode or Pressure-targeted ventilation”; It is a mode in which the volume of gas is provided till the target pressure is achieved. In this mode, the breaths are triggered by the patient and this mode may be used independently or in conjunction with other modes. The patient triggers the breaths in this mode, and it can be applied independently or in combination with other modes. Depending on airway compliance, lung compliance, and circuit compliance, the patient may get a varied tidal volume (VT). The two most frequently used pressure-targeted ventilation techniques are pressure-control (PC) and pressure-support (PS) (Goldsworthy & Graham, 2013).

During using pressure-support ventilation, the spontaneous breaths of patient are augmented with a predetermined amount of inspiratory pressure. In order to initiate spontaneous breaths while using this mode, the respiratory drive of the patient must be intact. Using PS negates the resistance of the ventilator circuit and artificial airway, which reduces the work of breathing. The primary parameters for the doctor to adjust are positive end expiratory pressure (PEEP), sensitivity, pressure-support level, and FiO2. This is regarded as complete ventilator support when high PS levels are necessary (Goldsworthy & Graham, 2013).

On the other hand, pressure-control ventilation is a mode in which the respiratory rate is controlled, and a predetermined amount of inspiratory pressure is augmented to each breath. The gas is given once it is triggered until the predetermined pressure is attained. If the patient takes spontaneous breaths, those breaths are also augmented by the predetermined inspiratory pressure. The doctor should set the PEEP, FiO2, sensitivity, inspiratory time, respiratory rate, and inspiratory-pressure limit. This mode is helpful for patients with limited lung compliance, such as those with ARDS, as a lung-protective strategy. This mode is effective in control high plateau pressures, which prevents the patient from developing barotrauma (Goldsworthy & Graham, 2013).

Volume-targeted ventilation mode

Also known as “volume-targeted ventilation or Volume-Control Mode”; this mode of ventilation ensures that the VT is constant during each breath that the ventilator delivers. The VT is preset and is delivered by the ventilator until the predetermined volume is attained. In this mode the ventilator performs all the Work of breathing (WOB), with no patient effort required. The ventilator delivers the entirely minute volume. This mode is helpful when the patient suffering from Apnea, for example, if the patient is experiencing a drug overdose or a neurological condition. A further reason for undertaking VTV is to completely rest the patient's respiratory muscles and diaphragm, allowing the underlying respiratory condition to heal. To enhance patient comfort, the sensitivity dial is adjusted to -1 to -2 cm, allowing the patient to initiate a ventilator breath with minimal effort. In contrast, if the patient is trying to begin a breath and the flow rate does not match inspiratory efforts, this mode may heighten the WOB, induce anxiety, and cause shortness of breath. This necessitates changing the flowrate setting right away (Goldsworthy & Graham, 2013).

The assist/control ventilation (A/C) mode is an example of VTV. The doctor must set the PEEP, FiO2, sensitivity, VT, and respiratory rate in order to ventilate the patient who needs A/C ventilation. A breath may be initiated by the patient and given at the predetermined VT. SIMV is another VTV mode. In SIMV, the patient will get a predetermined VT, much like in A/C mode. At the patient's own spontaneous VT, the patient may begin spontaneous breaths over the predetermined rate. Also, in this mode, the doctor must adjust the respiratory rate, PEEP, FiO2, VT, and sensitivity. This mode is beneficial for patients who have weak respiratory muscles and an intact respiratory drive. PS and SIMV are frequently related to each other. PS will offer additional support with spontaneous breaths. Historically, this mode was utilized as a method of weaning to progressively reduce the VT rate of predetermined breaths so that the patient could take over the WOB. According to research, this way of weaning takes a lengthy time to complete, which reduces the likelihood of success (Goldsworthy & Graham, 2013).

1.3 Literature review

The researcher reviewed a lot of literature related to the study topic from various sources. The Google Scholar databases, Web of Science, PubMed, and MEDLINE were explored for appropriate research paper published using the following terms: RDS, newborn babies, traditional pressure-limited ventilation modes, volume-targeted ventilation modes.

The publications' titles that resulted from the research were first checked to see if they were appropriate or not, and to ensure that they address the comparison of VTV mode with PLV ventilation mode for newborns. Then the abstracts were reviewed and, if suitable, the other parts of the study were reviewed.

Studies with results that are clinically relevant were given preference. Preference was given to large cohort studies and randomized controlled trials, but other related studies were also suitable for inclusion when the chosen research types were not available.

The bibliographies of extracted articles were explored for related publications. Oldest articles recognized in this manner were involved if the article was not covered by new recent research.

Many studies have focused on the use of VTV in comparison to PLV in premature infants. One of these literatures was a systematic Review made by Klingenberg et al. (2017) to ascertain whether using VTV in comparison to PLV results in lower rates of newborn mortality and BPD, as well as to ascertain if using VTV had an impact on outcomes like neurodevelopment, cranial ultrasound results, and air leak. In which, twenty randomized trials matched the criteria for inclusion, including four cross-over trials (88 newborns) and sixteen parallel trials (977 newborns). The researchers stated that there were no differences between VTV and PLV modes in the primary outcome, mortality during hospitalization. But there were some studies demonstrated that the primary outcome, BPD at 36 weeks of gestation, and death were reduced as a result of using of VTV mode. The authors in this review concluded that, as compared to infants ventilated using PLV modes, infants ventilated using VTV modes had lower rates of

length of ventilation, severe cranial ultrasound abnormalities, hypocarbia, pneumothoraxes, BPD, and mortality.

Another systematic review & meta-analysis performed by Peng et al. (2013) to evaluate the influence of VTV in comparison to PLV in premature infants. It showed that there was no evidence demonstrated that VTV mode decreases the incidence of mortality. While the duration of mechanical and ventilation incidence of BPD were both decreased as a result of the usage of VTV modes. Also, when compared to PLV modes, usage of VTV mode reduced mean airway pressure, days of supplemental oxygen administration, hypocarbia, failure of primary mode of ventilation, pneumothorax, periventricular leukomalacia (PVL), and intraventricular hemorrhage (IVH), grade 3/4 IVH among ventilated premature infants.

Moreover, Wang et al. (2015) carried out a systematic review and network meta-analysis; it includes 20 randomized controlled studies with a total of 2,832 participants assigned to one of 16 ventilation modes. It showed that the volume-controlled ventilation, SIMV + volume-guarantee, high-frequency oscillatory ventilation, and time cycled PLV modes are associated with decrease death rate compared to SIMV and pressure support ventilation mode. Regarding the occurrences of intraventricular hemorrhage and patent ductus arteriosus, the combined findings of the available ventilation modes were not markedly different.

Also, there is a study conducted by Akpan et al. (2021) and aimed to implement VTV to deduce hypocarbia in newborns with extremely low birth weight throughout the first week of life. In which the researchers analysed data on 28 and 77 participants in the baseline and postintervention periods, respectively. They stated that the usage of VTV raised from 39 percent to 65 percent. Nevertheless, there was no decrease in the incidence of hypocarbia (64% postintervention vs. 57% preintervention). The incidence of hypocarbia was comparable amongst VTV and other modes in the postintervention cohort; but the researchers observed earlier extubating and lower blood gas sampling in the VTV group. The researchers concluded that effectively increasing VTV in NICU

did not reduce hypocarbia throughout the first week of life. But the researchers noticed that VTV was safe and achieved additional advantageous outcomes.

Likewise, Chen and Chen (2019) performed a study to evaluate the effectiveness of VTV in comparison to PLV in newborns. In which, a total of 100 newborns who needed mechanical ventilation were included. PLV was applied for 50 newborns throughout period 1 and VTV was applied for 50 newborns throughout period 2. The following clinical outcomes were evaluated: intraventricular hemorrhage, hypoxemia, hypercarbia, hypocarbia, air leak syndrome, mechanical ventilation duration, retinopathy of prematurity, death rate, and combined outcome of BPD or mortality. The findings showed that there were no considerable differences between VTV and PLV regarding to BPD, hypoxemia, hypocarbia, air leak syndrome, and mechanical ventilation duration. While there were significantly decreases in hypercarbia, death rate, and combined outcome of mortality or BPD in VTV group in comparison to PLV group.

In addition, Chowdhury et al. (2013) conducted a Randomized trial to identify if VTV decreased the time required to meet weaning criteria in premature infants with ARDS when compared to PLV, and whether any difference was explained by better respiratory muscle strength and/or a lower WOB. In which, babies with less than 34 weeks of gestational age ventilated for less than 24 hours in the first week afterward birth were randomized to receive either VTV or PLV. It showed that 40 newborns with a median gestational age of 27 weeks (with a range of 23–33 weeks) were included. In both groups, it took almost the same amount of time to meet the weaning criteria. There were no significant differences regarding respiratory muscle strength, WOB or other outcomes (periventricular leukomalacia, intraventricular hemorrhage, pneumothorax, occurrence of patent ductus arteriosus, and duration of ventilation) between VTV and PLV groups, although the VTV group experienced fewer episodes of hypocarbia than the PLV group. They concluded that the using of VTV did not decrease the time of achieving the weaning requirements in premature infants with acute respiratory failure, and it was correlated to fewer episodes of hypocarbia.

Furthermore, there is a study conducted by Bhat et al. (2015) to identify if VTV or PLV minimized the time required to successfully extubating and if any difference was explained by a lower WOB, less thoracoabdominal asynchrony (TAA) or better respiratory muscle strength and related to a small number of hypocarbia episodes. In which newborns who born at more than or equal to 34 weeks of gestational age were randomized to PLV or VTV. The transdiaphragmatic pressure time product was used to assess the WOB, the maximal inflation (Pimax) and expiratory (Pemax) pressures were used to measure the respiratory muscle strength, and uncalibrated respiratory inductance plethysmography was used to measure the TAA. Forty newborns were recruited, with a median gestational age of 39 (range 34–42) weeks. There were no differences between two groups regarding to time required to successfully extubating, respiratory muscle strength or the TAA findings and WOB. In the VTV group, the median number of hypocarbia episodes was 1.5, with a range of 0 to 8, compared to 4, with a range of 1-13 in the PLV group.

Additionally, in a study of Hatch et al. (2021) the authors stated that the BPD has been connected to greater rates of readmission, longer durations of stay in the NICU, neurodevelopmental impairment, and higher health care usage in the early years of life. Also, BPD rates is less likely when VTV is used compared to PLV. They concluded that the quality improvement interventions were linked with improved VTV usage, however there are no changes in evaluated clinical outcomes.

Regarding the benefits of volume-targeted ventilation, there was a study conducted by Donn and Boon (2009) and showed that the use of VTV among premature infants with respiratory failure leads to slight but clinically significant improvements in short-term pulmonary outcomes, involving BPD.

Also, there was a study conducted by Claure and Bancalari (2008) and showed that the suggested advantages of VTV on respiratory outcome have not been fully confirmed by the current evidence. Certain trends indicate potential advantages, but these require to be additional investigated. The effectiveness of VTV may be method dependent and may also be affected by the magnitude of the volume targeted.

Regarding the agreement of the studies or their differences in their results, evidence has suggested that the usage of VTV lead to improved outcomes in premature infants who need mechanical ventilation in NICU (Pasley, 2021). Also, evidence suggests that the VTV mode led to decrease rates of mortality or BPD, compared with BPD (Hodgson et al., 2020).

In addition, there are studies that agree that the volume-targeted ventilation is no longer regarded as an experimental therapy and is currently commonly utilized in NICUs. It is considered safe and efficient and sustains short-term benefits like decreasing the ventilation duration and prevent related complications. Large multi-center trials will be required to study longer term clinical outcomes because there is a lack of data on these outcomes. However, these studies may be difficult to implement due to the differing practices of ventilation strategies that are applied between the different units. Therefore, in order to make sure that volume-targeting is accomplished safely and effectively, clinicians must get familiar with the modes and equipment utilized to provide VTV on their unit (Chitty & Sinha, 2015).

Finally, there are many differences in practice that present when it comes to the ventilator management of premature newborns. This is a result of developing technology in ventilator modes, performance, and its use to support premature newborns. There is currently no ventilator that has been demonstrated to be superior to others. Also, there is no definite consensus on which ventilator mode is best to use as the primary mode in premature newborns with RDS. The numerous research mentioned illustrate the difficulty in making any clear recommendations. While VTV shows some promise in certain trials, these trials were not powered to conclude considerable declines in morbidity or mortality among premature newborns. Thus, larger studies evaluating the results of various ventilation modes as primary support are required specifically targeting population (Ganguly et al., 2020).

Chapter Two

Methods

2.1 Research Design

The research design was randomized controlled trials design.

The researcher selected this design because it is one type of clinical trial and considered the most reliable way to compare treatments. Also, because of the RCT seeks to identify the optimal treatment by comparing a newer treatment with an existing treatment; two (or more) current therapies; and a new treatment and no treatment, or a placebo (where there is no existing treatment). In RCTs, a comparison is made between two or more groups of individuals. In which one (or more) experimental group(s) involves individuals who undergoing new treatments, and control group involves individuals who undergoing current standard treatment (MRC Clinical Trials Unit, 2018).

2.2 Study Population

The population was all the premature babies who were admitted to neonatal intensive care unit at Jenin governmental hospital with respiratory distress syndrome. The average number of these premature is about 20-30 premature babies monthly according to Jenin governmental hospital.

- Experimental group: premature babies who were admitted to intensive care unit at Jenin governmental hospital with respiratory distress syndrome and put on volume-targeted ventilation mode.
- Control group: premature babies who were admitted to intensive care unit at Jenin governmental hospital with respiratory distress syndrome and maintained on standard treatment (Traditional pressure-limited ventilation mode).

2.3 Study Setting

This study was performed in NICU department at Jenin governmental hospital, Westbank, Palestine.

The Jenin governmental hospital is located in Jenin, a city in the West Bank of Palestine, and provides acute care services. The hospital has a level two neonatal intensive care unit (NICU) that caters to critically ill newborns, staffed by a team of neonatologists, pediatricians, and nurses who provide 24-hour care. The NICU is equipped with advanced medical equipment such as ventilators, incubators, and phototherapy lights,total number of bed 206 , in NICU 26 incubator ,14 incubator in the first NICU and 12 in the second NICU. The hospital has social workers who provide emotional and psychological support to families during their time in the NICU (Palmer, et al., 2020).

2.4 Study Period

This study was performed between September 2021 to August 2022.

2.5 Sample Size

The total sample size was 80 patients (40 patients from Experimental (VTV) group and 40 patients from Control (PVL) group).

The sample size was calculated by an online sample size calculator that is available on the "Select Statistical Services" website. Which is used to determine the appropriate sample size (Select Statistical Services Limited, 2018).

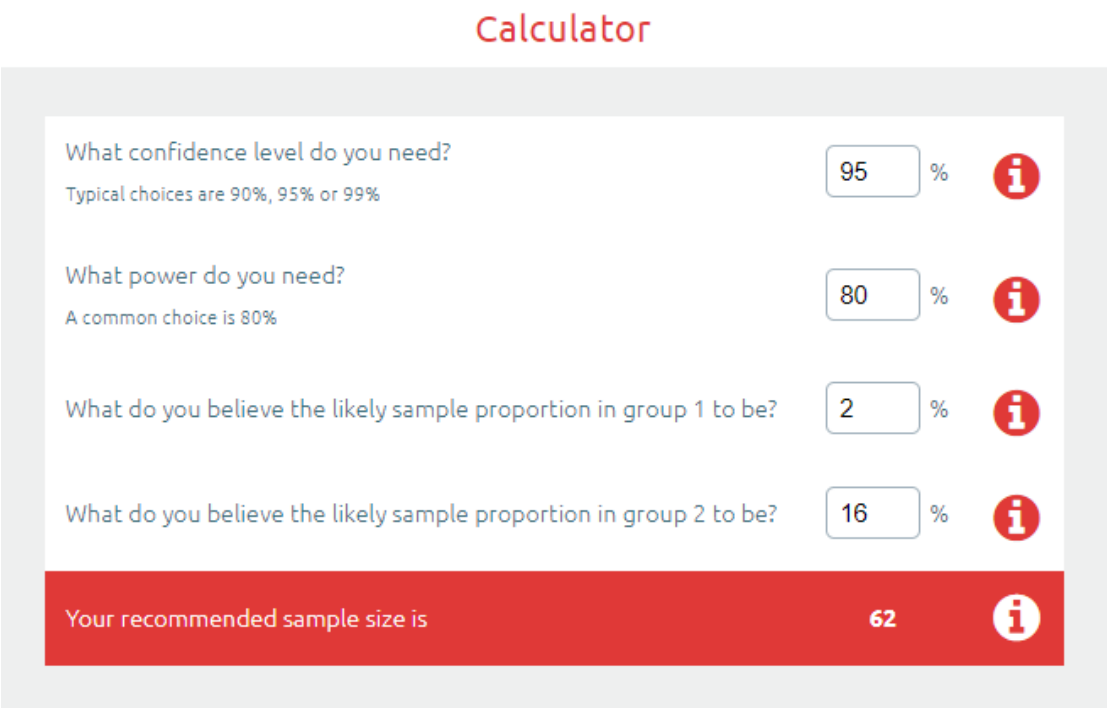
Calculation of the sample size is based on the following study

The mortality rate was significantly lower (p=0.031) in the VTV group (one patient) compared with PLV group (eight patients) (Chen & Chen, 2019).

We need 62 patients regarding the calculation. We add 10% of the sample to cover drop out, it will be 7+62= 69. We decided to recruit 40 patients in each group.

Figure 3

Calculation of the sample size



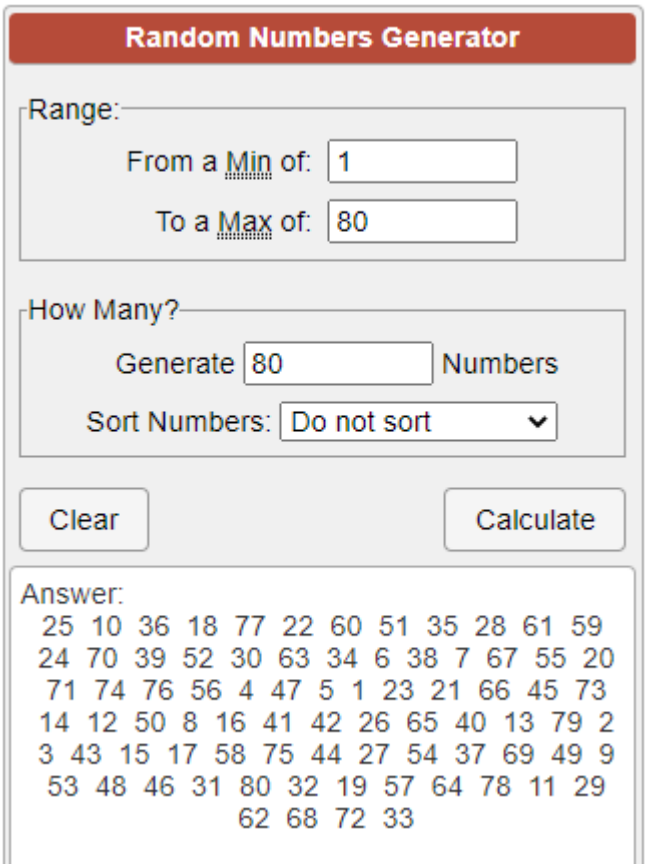
2.6 Sampling Technique

Randomization: The researcher selected this method because of the randomization is the best way of ensuring that the results of trials are not biased by the way participants in each group are selected.

Randomization was accomplished through the use of opaque and well-sealed envelopes. Random Allocation software 1.0 was used to generate the sequence on a computer. Once the random sequence was generated, the numbers were assigned to the participants in the order in which they were recruited. This process ensures that the allocation of participants to each group was unbiased and free from any potential confounding factors. The number was imprinted on envelopes, each envelope had a sequential number and was marked with the group type. When the patients were recruited for the study, the envelopes were opened to determine which group they would be assigned to. In this prospective randomized controlled trial, 80 patients were randomly assigned to one of two groups, each with 40 individuals.

Figure 4

sampling technique



2.7 Inclusion & Exclusion Criteria

Inclusion Criteria

- Premature babies who were admitted to NICU at Jenin governmental hospital with RDS and need mechanical ventilation.
- Premature babies whose gestational age was 24 weeks or more.
- Premature babies with no lethal congenital and chromosomal anomalies (heart disease, metabolic disease … etc.).
- Premature babies with no confirmed or suspected sepsis/pneumonia.
- Premature babies whose parents were willing to participate in the study.

Exclusion Criteria

- Premature babies whose gestational age is less than 24 weeks.
- Premature babies with lethal congenital and chromosomal anomalies (heart disease, metabolic disease … etc.).
- Premature babies with confirmed or suspected sepsis/pneumonia.
- Premature babies whose parents were not willing to participate in the study.

2.8 Study Tool

The tool of the study was patient data sheet. It was used for data collection. After reviewing many previous studies (Chen and Chen 2019; Claure and Bancalari 2008; Donn and Boon 2009; Klingenberg et al. 2017; Peng et al. 2013), the study tool was built and prepared by the researcher with the help of the study supervisor. It consisted of several parts, including general characteristics (Gender, gestational age, current age, age at intubation, type of delivery, birth weight and current weight), clinical outcomes (BP, RR, HR, SPO2, tidal volumes, and FiO2); length of management related to (length of intubation, and oxygen therapy duration); and presence of any complications (Appendix A).

The general characteristics of the participants were evaluated by assess the participants by the researcher and by checking the participants' file. The clinical outcomes were evaluated every 3 hours during first 24 hours. Also, the researcher measured the length of intubation duration during staying at NICU and oxygen therapy duration during staying at NICU. As for complications, the researcher assessed the participants for the present or absent of Pneumothorax, Mortality before discharge, and others complication (such as intra ventricular haemorrhage (IVH)).

2.9 Validity of study tool

Validity refers to "whether the study tool measures what it intends to measure". The study tool was reviewed by the supervisor, and 7 experts in the study field (two paediatric intensivist, two neonatal intensive nurses, two researchers and one statistician) intensive to evaluate it, provide judgment and suggestions. All suggestions

were taken into consideration. These suggestions included remove of ABGs, chronological age, 1-min Apgar score, 5-min Apgar score, hypocarbia, and hypercarbia.

2.10 Pilot Study

It was done before starting actual data collection on 10 patients (5 VTV and 5 PLV). It was performed for several purposes, including: to determine if there are any problems in the data sheet, evaluate the actual time required to fill out the data sheet and to ensure the accuracy, validity, suitability, and reliability of the data sheet. The pilot study sample was included in the main study sample because it did not contain any problems.

2.11 Data Collection

Data was collected after obtaining a formal approval from Institutional Review Board (IRB) and the ministry of health (MOH). It was collected by the researcher herself with some assistance from health team in the period between Nov. 2021 to mid-June 2022 using patient data sheet which consists of several parts, including Patient's information; Clinical outcomes; duration of intubation and oxygen therapy; and complications. The researcher took all ethical considerations into account. The purpose of the study was explained, and appropriate instructions were given to the parents before conducting the study. The researcher, who works in the department, followed up on the overall sample size. In the case that the researcher was present in the department, she independently recorded the readings on the data sheet; however, in the event that the researcher was absent, she took the data that was already kept on the hospital system.

Variables

Independent variables: General characteristics of the premature baby including gender, gestational age, current age, birth weight, current weight, modes of ventilation (volume-targeted ventilation mode and traditional pressure-limited ventilation mode) and type of delivery.

Dependent variables: Clinical outcomes (BP, RR, HR, SaO2, tidal volumes and FiO2), length of intubation duration, oxygen therapy duration and presence of any complications.

2.12 Statistical Analysis

Microsoft Office applications was used, such as Microsoft Word and Microsoft Excel. Also, the researcher used SPSS V25.0 program for data entry and analysis with the assistance of a statistician to do the appropriate statistical tests.

"Descriptive statistics (frequencies, percentages, Means, Standard Deviations) were used. The following Tests and Methods were used to analyse the results assuming that the P-Value < 0.05 is considered significant:"

- **Chi-Square test:** tests the differences in percentages between the study groups of patients for qualitative variables such as: gender, gestational age, current age, birth weight, current weight, type of delivery, the complications.

- **Two Independent Samples T test:** test the differences in means between the study groups for quantitative variables such as: systolic blood pressure, diastolic blood pressure, respiratory rate, heart rate, oxygen saturation Spo2, tidal volumes, FiO2, the duration of intubation and oxygen therapy.

2.13 Ethical Consideration

As the research involves human participants, it is necessary to follow strict ethical principles, preserve all participant's rights and abide to all scientific research ethics. Approvals were taken from the Ministry of Health (Appendix B) as well as the approval of the Institutional Review Board (IRB) (Appendix C). The participant's parents were asked to give their consent and they were assured that participation or information provided would not be used against them. They were also assured of their right of confidentiality. Confidentiality was taken into consideration regarding data obtained from clinical files. The cases were kept anonymous without names and just with codes for data analysis. Participants did not expose to any physical harm, inconvenience, or danger.

Chapter Three

Results

This chapter includes the main findings of the study according to aims, hypotheses, and questions.

3.1 Patients' information

Table 1

Comparisons between VTV group and PLV group regarding the patient's gender and age (N=80)

	Category	Group		Total	P-value*
		VTV (N=40)	PLV (N=40)	(N=80)	
Gender	Male	27(67.5%)	15(37.5%)	42(52.5%)	0.007
	Female	13(32.5%)	25(62.5%)	38(47.5%)	
Gestational age (weeks)	29	3(7.5%)	6(15%)	9(11.3%)	0.653
	30	3(7.5%)	4(10%)	7(8.8%)	
	31	4(10%)	3(7.5%)	7(8.8%)	
	32	4(10%)	4(10%)	8(10%)	
	33	7(17.5%)	11(27.5%)	18(22.5%)	
	34	7(17.5%)	7(17.5%)	14(17.5%)	
	35	7(17.5%)	3(7.5%)	10(12.5%)	
	36	5(12.5%)	2(5%)	7(8.8%)	
Current age (days)	From 0-7 days	11(27.5%)	15(37.5%)	26(32.5%)	0.330
	From 8-14 days	12(30%)	13(32.5%)	25(31.3%)	
	From 15-21 days	10(25%)	10(25%)	20(25%)	
	From 22-28 days	7(17.5%)	2(5%)	9(11.3%)	

The P-values are related to the Chi-square test of independence for the qualitative variables and the Two independent samples T-test for the quantitative variables, and the numbers in the table represent N (%) or (Mean ± Standard deviation).

The results in the table (1) show that in regard to the patient's gender and age there are significant differences was seen between two groups related to gender. Also, the results show that there is no significant relationship between VTV group and PLV group, related to category of gestational age in weeks, as well as there is no significant relationship between VTV group and PLV group, related to category of current age in days.

The results show that the percentage of Males in VTV group (N=27, P=67.5%) is significantly higher than the percentage of Males in PLV group (N=15, P=37.5%), and the percentage of Females in VTV group (N=13, P=32.5%) is significantly lower than the percentage of Females in PLV group (N=25, P=62.5%), the P-value of the test is 0.007<0.05.

Table 2

Comparisons between VTV group and PLV group regarding the patient's weight and type of delivery (N=80)

	Category	Group		Total (N=80)	P-value*
		VTV (N=40)	PLV (N=40)		
Birth Weight (kg)	From 1 to 1.5 Kg	7(17.5%)	14(35%)	21(26.3%)	0.128
	From 1.51 to 2.5 Kg	18(45%)	19(47.5%)	37(46.3%)	
	From 2.51 to 3.5 Kg	14(35%)	7(17.5%)	21(26.3%)	
	More than 3.5 kg	1(2.5%)	0(0%)	1(1.3%)	
Current weight (kg)	From 1 to 1.5 Kg	5(12.5%)	13(32.5%)	18(22.5%)	0.010
	From 1.51 to 2.5 Kg	18(45%)	18(45%)	36(45%)	
	From 2.51 to 3.5 Kg	15(37.5%)	9(22.5%)	24(30%)	
	More than 3.5 kg	2(5%)	0(0%)	2(2.5%)	
Type of delivery	Normal vaginal delivery	13(32.5%)	17(42.5%)	30(37.5%)	0.356
	Cesarean section	27(67.5%)	23(57.5%)	50(62.5%)	

The P-values are related to the Chi-square test of independence for the qualitative variables and the Two independent samples T-test for the quantitative variables, and the numbers in the table represent N (%) or (Mean ± Standard deviation).

As for Patient's weight and type of delivery, the results in the table (2) show that there are significant differences between the two groups related to current weight. While there are no significant differences between the two groups related to birth weight and type of delivery.

The results show that the percentage of the current weight group (From 1 to 1.5 Kg) in VTV group (N=5, P=12.5%) is significantly lower than that in PLV group (N=13, P=32.5%), and the percentage of the current weight group (From 2.51 to 3.5 Kg) in VTV group (N=15, P=37.5%) is significantly higher than that in PLV group (N=9, P=22.5%), and the percentage of the current weight group (More than 3.5 kg) in VTV group (N=2, P=5%) is significantly higher than that in PLV group (N=0, P=0%), the P-value of the test is 0.010<0.05.

3.2 Clinical Outcomes

Table 3

Comparisons between VTV group and PLV group regarding the Systolic Blood Pressure (N=80)

Period in hours	Systolic Blood Pressure Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	68.95 ± 12.23	67.85 ± 9.89	68.4 ± 11.07	0.660
2nd three hours	70.2 ± 9.87	68.05 ± 10.63	69.13 ± 10.25	0.352
3rd three hours	69.28 ± 8.08	70.25 ± 9.19	69.76 ± 8.61	0.616
4th three hours	67.95 ± 7.99	68.95 ± 8.58	68.45 ± 8.26	0.591
5th three hours	70.7 ± 10.24	70.31 ± 8.25	70.51 ± 9.25	0.852
6th three hours	69.63 ± 9.47	71.82 ± 8	70.71 ± 8.79	0.270
7th three hours	70.3 ± 9.19	70.05 ± 8.47	70.18 ± 8.78	0.901
8th three hours	70.98 ± 7.41	69.41 ± 6.46	70.2 ± 6.96	0.321
The total 24 hours	69.75 ± 6.31	69.51 ± 6.09	69.63 ± 6.16	0.863

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation)

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The results in the table (3) above show that there are no significant differences at 0.05 level between VTV group and PLV group in all Systolic Blood Pressure scales during the first 24 hours, all the P-values of the tests are >0.05.

Figure 5

Comparisons between VTV group and PLV group regarding the Systolic Blood Pressure (N=80)

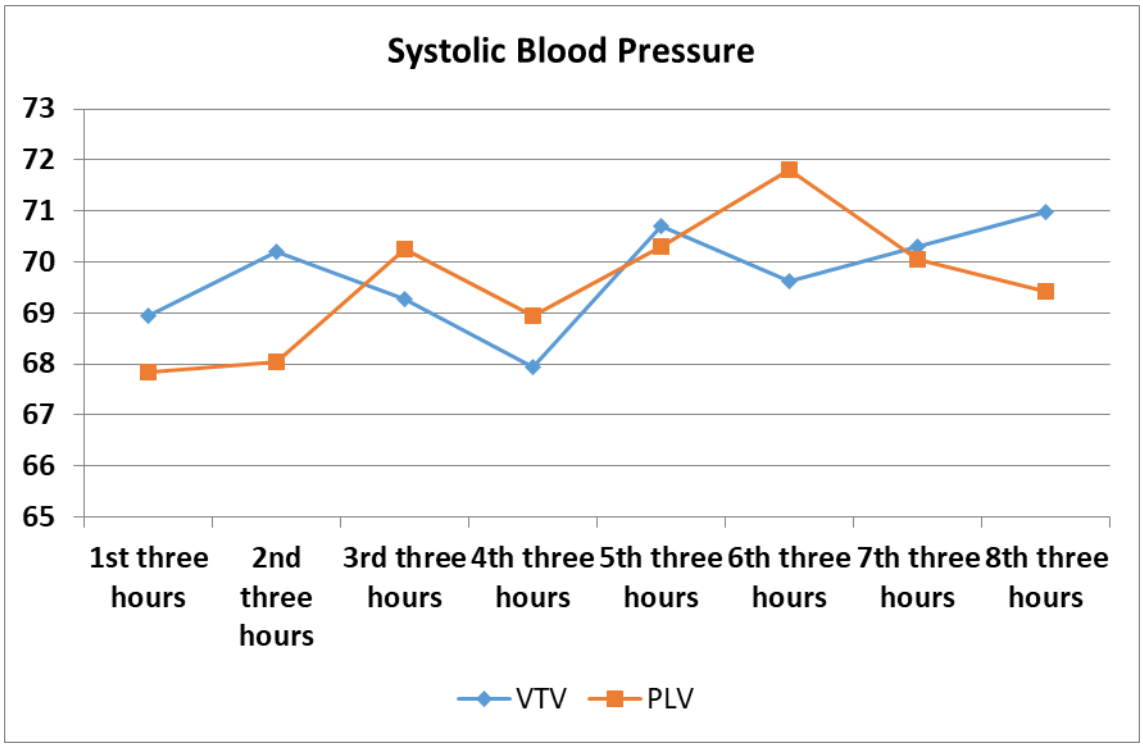

Table 4

Comparisons between VTV group and PLV group regarding the Diastolic Blood Pressure (N=80)

Time period in hours	Diastolic Blood Pressure Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	36.55 ± 8.52	37.53 ± 8.01	37.04 ± 8.23	0.599
2nd three hours	37.1 ± 6.77	35.6 ± 7.68	36.35 ± 7.23	0.357
3rd three hours	36.83 ± 6.54	38 ± 6.1	37.41 ± 6.31	0.409
4th three hours	36.98 ± 6.89	37.38 ± 7.5	37.18 ± 7.16	0.804
5th three hours	37.8 ± 6.79	39.41 ± 7.55	38.59 ± 7.17	0.322
6th three hours	38.73 ± 8.03	38.46 ± 6.9	38.59 ± 7.45	0.876
7th three hours	39.18 ± 7.79	37.69 ± 7.03	38.44 ± 7.41	0.378
8th three hours	38.15 ± 5.99	37.15 ± 5.08	37.66 ± 5.54	0.428
The total 24 hours	37.66 ± 5.07	37.54 ± 4.23	37.6 ± 4.64	0.910

The P-values are related to the Two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (4) above show that there are no significant differences at 0.05 level between VTV group and PLV group in all Diastolic Blood Pressure scales during the first 24 hours, all the P-values of the tests are >0.05.

Figure 6

Comparisons between VTV group and PLV group regarding the Diastolic Blood Pressure (N=80)

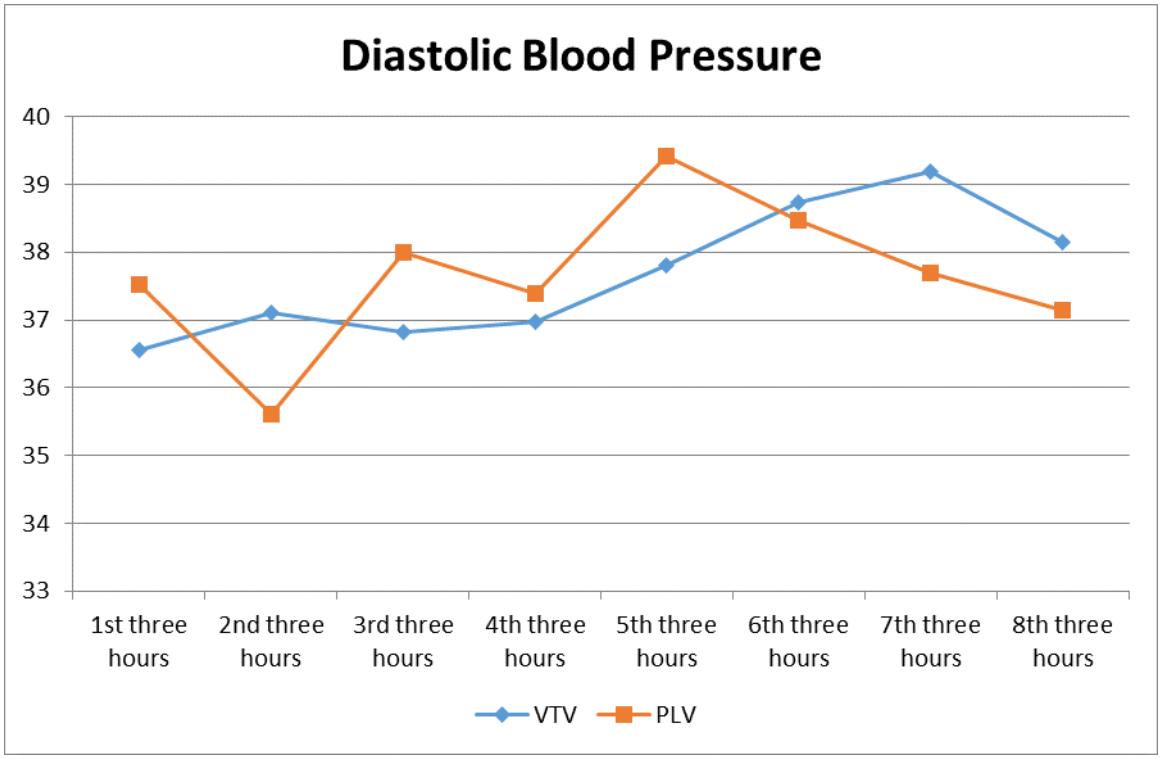

Table 5

Comparisons between VTV group and PLV group regarding the Respiratory Rate (N=80)

Respiratory Rate	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	36.58 ± 5.09	38.05 ± 4.94	37.31 ± 5.04	0.192
2nd three hours	37.1 ± 5.31	38.5 ± 5.26	37.8 ± 5.3	0.240
3rd three hours	37 ± 4.96	38.77 ± 5.36	37.87 ± 5.2	0.132
4th three hours	35.61 ± 5.05	38.03 ± 5.16	36.82 ± 5.22	0.042
5th three hours	36.84 ± 4.71	37.46 ± 6.52	37.15 ± 5.64	0.639
6th three hours	36.63 ± 5.53	37.78 ± 6.5	37.2 ± 6.02	0.411
7th three hours	37.34 ± 4.97	38.76 ± 6.08	38.04 ± 5.56	0.273
8th three hours	36.37 ± 4.77	38.78 ± 6.49	37.56 ± 5.77	0.038
The total 24 hours	36.63 ± 4.19	38.2 ± 4.91	37.42 ± 4.61	0.130

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (5) above show that there are significant differences at 0.05 level between VTV group and PLV group in the respiratory rate only at the fourth 3 hours and at the eighth 3 hours.

Regarding the respiratory rate at the fourth 3 hours, the results show that the mean in VTV group (Mean=35.61) is significantly lower than the mean in PLV group (Mean=38.03), the P-value of the test is 0.042<0.05. Regarding the respiratory rate at the eighth 3 hours, the results also show that the mean in VTV group (Mean=36.37) is significantly lower than the mean in PLV group (Mean=38.78), the P-value of the test is 0.038<0.05.

Figure 7

Comparisons between VTV group and PLV group regarding the Respiratory Rate (N=80)

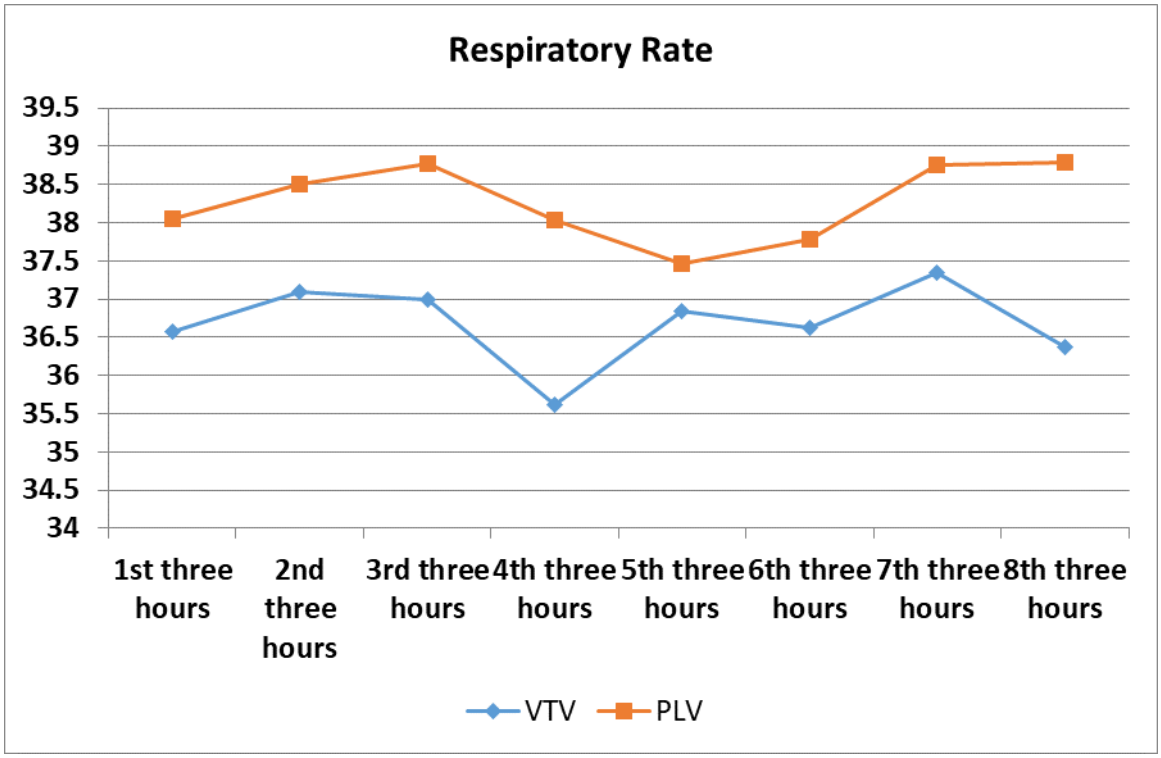

Table 6

Comparisons between VTV group and PLV group regarding the Heart Rate (N=80)

Heart Rate	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	134.95 ± 11.19	140.38 ± 11.6	137.66 ± 11.65	0.036*
2nd three hours	137.15 ± 9.81	139.95 ± 12.22	138.55 ± 11.1	0.262
3rd three hours	135.98 ± 10.65	140.65 ± 12	138.31 ± 11.52	0.069
4th three hours	135.45 ± 14.26	139.43 ± 11.4	137.44 ± 12.98	0.172
5th three hours	137.28 ± 10.97	139.38 ± 10.29	138.32 ± 10.63	0.381
6th three hours	138.25 ± 11.05	138.95 ± 10.23	138.59 ± 10.59	0.771
7th three hours	136.63 ± 11.29	137.33 ± 10.26	136.97 ± 10.73	0.771
8th three hours	137.05 ± 8.31	140.38 ± 11.93	138.7 ± 10.33	0.153
The total 24 hours	136.59 ± 9.27	139.79 ± 9.66	138.19 ± 9.54	0.134

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (6) above show that there are significant differences at 0.05 level between VTV group and PLV group in the heart rate only at the first 3 hours, the mean in VTV group (Mean=134.95) is significantly lower than the mean in PLV group (Mean=140.38), the P-value of the test is 0.036<0.05.

Figure 8

Comparisons between VTV group and PLV group regarding the Heart Rate (N=80)

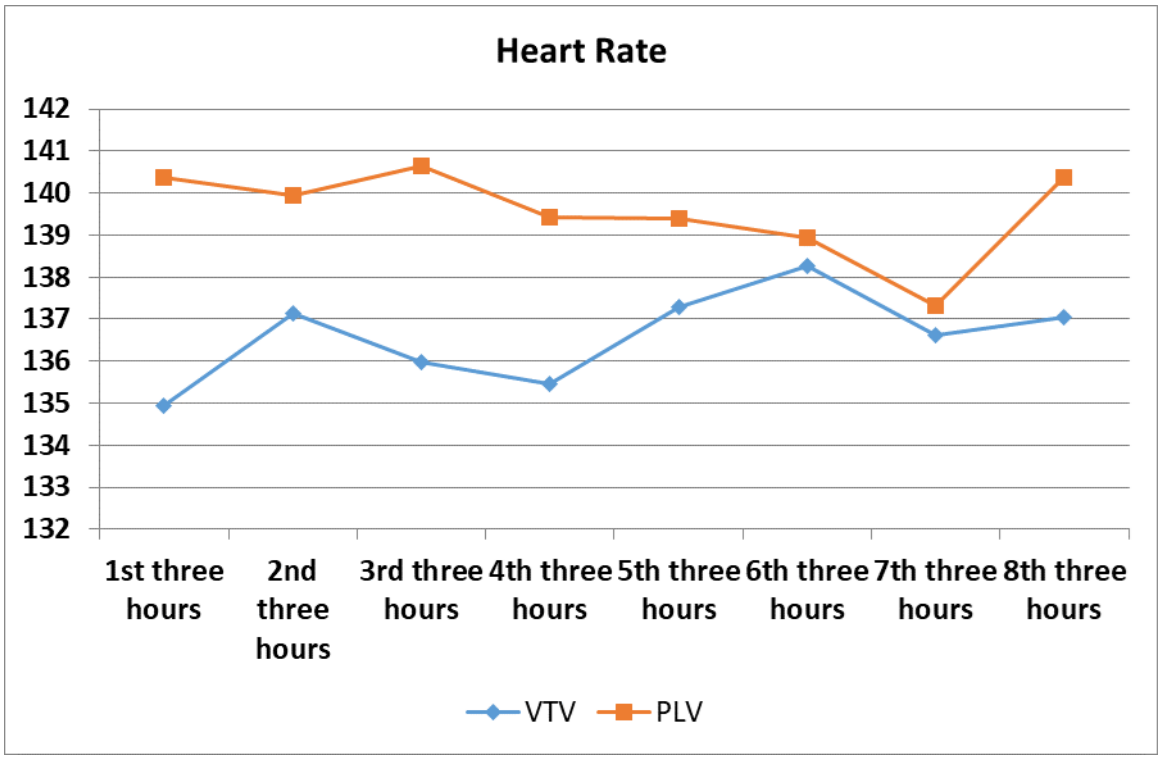

Table 7

Comparisons between VTV group and PLV group regarding the Oxygen Saturation Spo2 (N=80)

Oxygen Saturation Spo2	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	99.38 ± 1.43	96.88 ± 3.96	98.13 ± 3.22	0.000*
2nd three hours	98.13 ± 1.94	97.05 ± 4.41	97.59 ± 3.43	0.162
3rd three hours	97.6 ± 1.68	96.25 ± 4.88	96.93 ± 3.69	0.102
4th three hours	97.08 ± 1.64	95.48 ± 4.69	96.28 ± 3.58	0.045*
5th three hours	97.33 ± 1.87	95.77 ± 4.49	96.56 ± 3.49	0.047*
6th three hours	97.18 ± 2.01	95.28 ± 5.73	96.24 ± 4.35	0.052
7th three hours	97.08 ± 1.87	96.08 ± 3.06	96.58 ± 2.57	0.084
8th three hours	97.85 ± 2.08	95.97 ± 3.79	96.92 ± 3.17	0.008*
The total 24 hours	97.7 ± 1	95.86 ± 4	96.78 ± 3.04	0.006*

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (7) above show that there are significant differences at 0.05 level between VTV group and PLV group in the oxygen saturation Spo2 at the first 3 hours, at the fourth 3 hours, at the fifth 3 hours, at the eighth 3 hours, and at the total 24 hours.

Regarding the oxygen saturation Spo2 at the first 3 hours, the results show that the mean in VTV group (Mean=99.38) is significantly higher than the mean in PLV group (Mean=96.88), the P-value of the test is <0.001.

Regarding the oxygen saturation Spo2 at the fourth 3 hours, the results show that the mean in VTV group (Mean=97.08) is significantly higher than the mean in PLV group (Mean=95.48), the P-value of the test is 0.045<0.05.

Regarding the oxygen saturation Spo2 at the fifth 3 hours, the results also show that the mean in VTV group (Mean=97.33) is significantly higher than the mean in PLV group (Mean=95.77), the P-value of the test is 0.047<0.05.

Regarding the oxygen saturation Spo2 at the eighth 3 hours, the results also show that the mean in VTV group (Mean=97.85) is significantly higher than the mean in PLV group (Mean=95.97), the P-value of the test is 0.008<0.05.

Regarding the oxygen saturation Spo2 at the total 24 hours, the results show that the mean in VTV group (Mean=97.7) is significantly higher than the mean in PLV group (Mean=95.86), the P-value of the test is 0.006<0.05.

Figure 9

Comparisons between VTV group and PLV group regarding Oxygen Saturation (N=80)

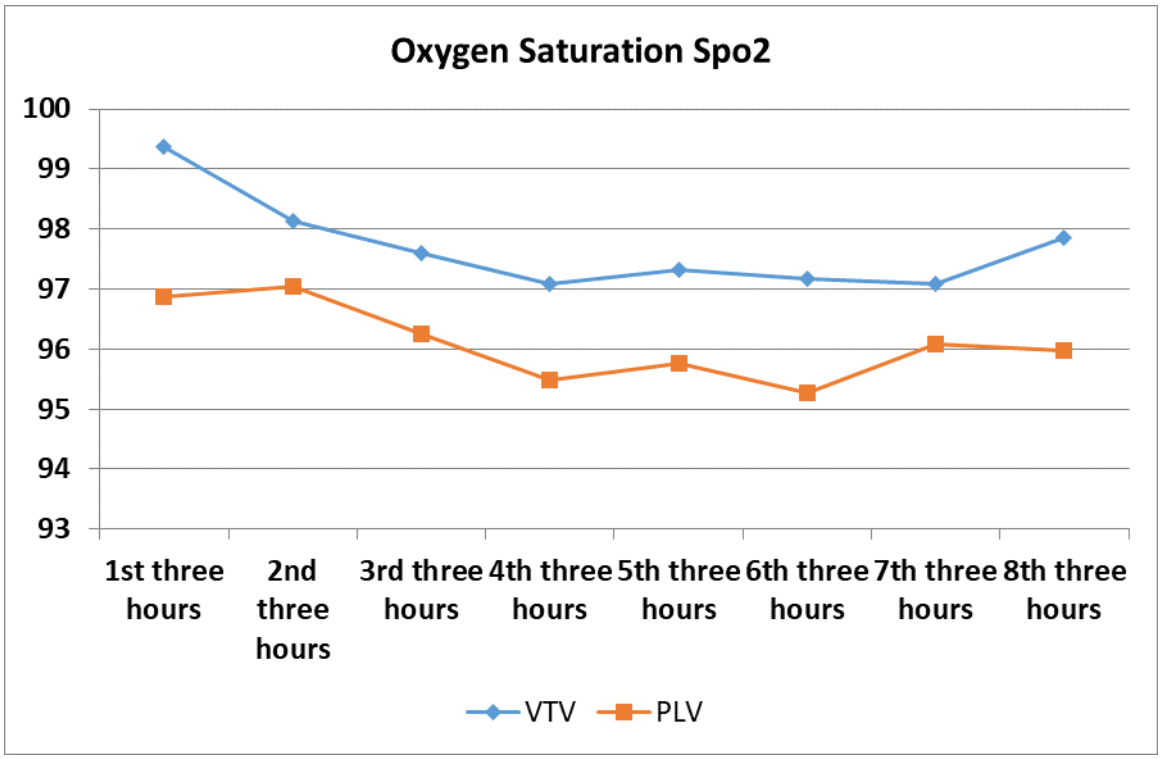

Table 8

Comparisons between VTV group and PLV group regarding the Tidal Volumes (N=80)

Tidal Volumes	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	15.7 ± 5.74	15.88 ± 14.1	15.79 ± 10.7	0.942
2nd three hours	15.6 ± 5.71	13.9 ± 5.78	14.75 ± 5.77	0.190
3rd three hours	15.56 ± 5.5	13.92 ± 5.81	14.75 ± 5.68	0.207
4th three hours	15.54 ± 5.97	13.41 ± 5.88	14.49 ± 5.98	0.140
5th three hours	15.79 ± 5.95	13.47 ± 6.01	14.7 ± 6.04	0.125
6th three hours	15.76 ± 5.84	13.57 ± 6.18	14.73 ± 6.05	0.149
7th three hours	15.29 ± 5.99	13.2 ± 5.77	14.31 ± 5.94	0.161
8th three hours	15.45 ± 6.01	13.2 ± 5.76	14.38 ± 5.95	0.134
The total 24 hours	15.76 ± 5.59	14.38 ± 6.33	15.07 ± 5.98	0.305

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (8) above show that there are no significant differences at 0.05 level between VTV group and PLV group in all Tidal Volumes scales during the first 24 hours, all the P-values of the tests are >0.05.

Figure 10

Comparisons between VTV group and PLV group regarding the Tidal Volumes (N=80)

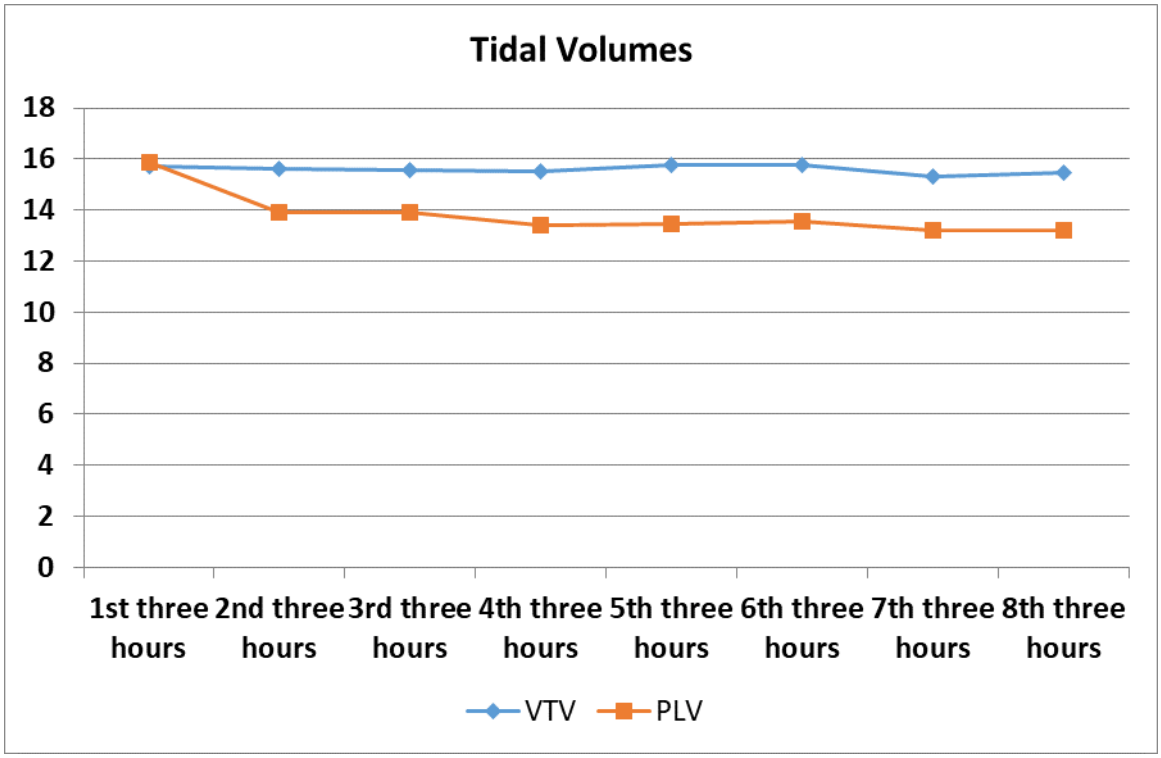

Table 9

Comparisons between VTV group and PLV group regarding the FiO2 (N=80)

FiO2	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
1st three hours	88.5 ± 20.1	84.38 ± 23.13	86.44 ± 21.63	0.397
2nd three hours	70.78 ± 22.86	70.53 ± 27.89	70.65 ± 25.34	0.965
3rd three hours	58.36 ± 24.37	64 ± 29.11	61.14 ± 26.79	0.359
4th three hours	53.76 ± 22.24	61.79 ± 28.67	57.72 ± 25.74	0.204
5th three hours	50.61 ± 20.77	62.52 ± 26.28	56.45 ± 24.18	0.067
6th three hours	44.3 ± 22.9	66.26 ± 29.64	55.28 ± 28.48	0.004*
7th three hours	38.19 ± 25.18	62.74 ± 32.36	50.46 ± 31.28	0.003*
8th three hours	33.96 ± 22.32	57.19 ± 32.23	45.57 ± 29.85	0.003*
The total 24 hours	54.34 ± 16.47	62.35 ± 23.31	58.34 ± 20.46	0.080

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (9) above show that there are significant differences at 0.05 level between VTV group and PLV group in the FiO2 only at the sixth 3 hours, at the seventh 3 hours, and at the eighth 3 hours.

Regarding the FiO2 at the sixth 3 hours, the results show that the mean in VTV group (Mean=44.3) is significantly lower than the mean in PLV group (Mean=66.26), the P-value of the test is 0.004<0.05.

Regarding the FiO2 at the seventh 3 hours, the results show that the mean in VTV group (Mean=38.19) is significantly lower than the mean in PLV group (Mean=62.74), the P-value of the test is 0.003<0.05.

And regarding the FiO2 at the eighth 3 hours, the results also show that the mean in VTV group (Mean=33.96) is significantly lower than the mean in PLV group (Mean=57.19), the P-value of the test is 0.003<0.05.

3.3 Duration of intubation and oxygen therapy

Table 10

Comparisons between VTV group and PLV group regarding the Duration of Intubation and Oxygen Therapy (N=80)

Variable	Group		Total	P-value*
	VTV (N=40)	PLV (N=40)	(N=80)	
Length of intubation duration during staying at NICU	2.66 ± 4.98	2.73 ± 3.22	2.7 ± 4.17	0.935
Oxygen therapy duration during staying at NICU	2.78 ± 3.51	2.95 ± 3.21	2.86 ± 3.35	0.829

The P-values are related to the two independent samples T-test and the numbers in the table represent (Mean ± Standard deviation).

The results in the table (10) above show that there are no significant differences at 0.05 level between VTV group and PLV group in the Length of intubation duration during staying at NICU and in the Oxygen therapy duration during staying at NICU, all the P-values of the tests are >0.05.

3.4 Complications

The results in the table (D1) in Appendix D above show that there are no significant differences at 0.05 level between VTV group and PLV group related to pneumothorax, surfactant, and mortality before discharge.

Chapter Four

Discussions and Conclusions

4.1 Discussion

In this randomized controlled study, the researcher aimed to evaluate the effects of volume-targeted ventilation (VTV) and traditional pressure-limited ventilation (PLV) on Clinical outcomes (BP, RR, HR, SaO2, Tidal volumes and FiO2), length of intubation duration, Oxygen therapy duration and presence of any complications among premature babies with RDS.

- **Clinical Outcomes**

Regarding participant's characteristics, it focused on gender, gestational age (weeks), current age (days), birth weight (kg), current weight (kg), and type of delivery.

Regarding to gender, the total number of male participants is 42 (27 VTV and 15 PLV), while the total number of female is 38 (13 VTV and 25 PLV), the study findings showed that there are significant differences between VTV group and PLV group related to gender (P value < 0.05), whereas the percentage of males in VTV group is significantly higher than in the PLV group, while the percentage of females in PLV group is significantly higher than the percentage of female in the VTV group.

As for gestational age, birth weight, current age and type of delivery, there are no significant differences between VTV group and PLV group (P value > 0.05).

The highest current weight category is from 1.51 to 2.5 Kg, while the lowest is more than 3.5 kg. There are significant differences between VTV group and PLV group related to current weight (P value < 0.05) in the interest of the VTV group.

- **Duration of intubation and oxygen therapy**

This study shows that there are no significant differences between VTV group and PLV group related to length of intubation duration during staying at NICU and in the Oxygen therapy duration during staying at NICU.

The results of this study match with the study of Bhat et al. (2015) which indicated that "VTV compared to PLV did not reduce the time to successful extubating". Likewise, it corresponds with the study of Chowdhury et al. (2013) which concluded that "In prematurely born infants with acute respiratory distress, use of VTV did not reduce the time to reach weaning criteria". Moreover, it agrees with the study of Chen & Chen (2019) which demonstrated that "there was no significant difference between VTV and PLV in the duration of mechanical ventilation".

These findings differ from the results of Claure & Bancalari (2008) which stated that "volume-targeted ventilation indicates faster weaning and shorter duration of mechanical ventilation, but this has not resulted in better respiratory outcome". As well as it differs from the results of McCallion et al. (2005) which showed that volume-targeted ventilation resulted in significant reductions in duration of ventilation. Also, our results differ from the result of Peng et al. (2013) which stated that "premature infants ventilated using VTV modes had reduced duration of mechanical ventilation". Similar to that, a meta-analysis revealed a statistically significant decrease in the length of ventilation (Wheeler, et al 2011).

- **FiO2**

Regarding FiO2, there were considerable differences between the VTV group and the PLV group. In comparison to the PLV group, the patients in the VTV group needed less FiO2. This study's findings conflict with those of Piotrowski (2007), who found that there were differences in FiO2 levels between the VTV and PLV groups in the first six hours of life and in the usage of surfactants (higher FiO2 and more surfactant used in the VTV group).

- **SPO2**

In the current investigation, there is a sizable discrepancy in favour of the VTV group regarding the SPO2 when compared to the PLV group. These results are consistent with a study by Enomoto et al., (2014) which showed that volume assured ventilation will reduce SpO2 variation, which prevents hypoxia and may lead to a better neonatal prognosis.

- **Days of supplemental oxygen administration**

Between the VTV and PLV groups, there was no statistically significant difference in the length of oxygen therapy throughout NICU stays, according to the current study. These results are inconsistent with the systemic review study, which found that VTV modes reduced the number of days that patients needed to take supplementary oxygen (Peng et al., 2013).

- **Hemodynamic Effects of Ventilation Modes**

Recognizing how care methods affect hemodynamics is crucial. In the present investigation, there were no statistically significant variations in hemodynamic parameters, such as heart rate, systolic and diastolic pressure, between the VTV and PLV groups. Clinical trials have examined the cardiovascular effects of standard mechanical ventilation techniques, but the effects of various breathing techniques on hemodynamics have received less attention. Volume targeted ventilation, as opposed to pressure limited ventilation, has been linked to a lower risk of death, chronic lung illness, cerebral injury, and air leak, according to a Cochrane review (Klingenberg et al., 2017). These findings may be related to volume targeted ventilation, which is linked to a steady inspiratory pressure that could result in a stable alveolar pressure and less fluctuation in pulmonary vascular resistance (PVR) (RV afterload) and pulmonary blood flow (PBF) (LV preload). Although volume guided ventilation may have a positive effect on hemodynamics and short-term outcomes, this is still only early data that has to be confirmed in sizable trials (Bugiera et al., 2020).

- **Complications**

The optional ventilation mode known as VTV has been examined the most in depth and widely in premature new-borns. In the past ten years, algorithms for ventilator software have been created by fusing PLV with volume targeting. As a result, Peak Inspiratory Pressure (PIP) automatically adapts to recognize and overcome unexpected changes in lung compliance. Reaching the desired volume results in greater volume discharge stability. The findings of the current study demonstrated that there are no significant differences in pneumothorax, surfactant, and mortality before to discharge between the

VTV group and PLV group. These results are consistent with research by Wheeler et al. (2011), which also found no evidence of an increase in any unfavourable outcomes associated with the use of VTV in comparison to PLV.

The results showed that the number of died patients in the PLV group higher than in the VTV, however there was no statistically significant difference but clinically is relevant. These results did not match the results of Wheeler et al. (2010) which stated that "infants ventilated using volume-targeted ventilation had reduced death/BPD, Pneumothorax, and periventricular leukomalacia/severe intraventricular hemorrhage (or other complication) Compared with PLV. In addition, the current study results did not differ from the results of Peng et al. (2013) related to death which indicated that "there was no evidence that infants ventilated with VTV mode had reduced death compared to infants ventilated using PLV modes". Similar to McCallion et al. (2005), who found that the rates of mortality and BPD were not substantially different between the two ventilator techniques (VTV and PLV), the results of the current study regarding the rate of death did not deviate from those findings.

4.2 Conclusions

VTV mode produced improved oxygen saturation values for SPO2, and FiO2 in comparison to PLV mode, The results showed that the number of died patients in the PLV group higher than in the VTV, however there was no statistically significant difference but clinically is relevant. No evidence of an increase in any unfavourable outcomes associated with the use of VTV in comparison to PLV. Also, there are no significant differences between VTV group and PLV group in systolic and diastolic blood pressure during the first 24 hours; tidal volumes during the first 24 hours; length of intubation duration at NICU; and oxygen therapy duration during staying at NICU.

4.3 Limitations

The researcher faced a limitation during the implementation of the study, these limitations are:

- The study had a small sample size, it may not be representative of the broader population of premature babies with RDS. This could limit the generalizability of the results.
- The study only followed patients for a short period of time, it may not have captured longer-term outcomes that could be important in evaluating the relative effectiveness of the two ventilation modes.

4.4 Recommendations

In the light of the study findings, the researcher recommends a set of practical recommendations that contribute to achieving the volume-targeted ventilation mode better than traditional pressure-limited ventilation mode; these recommendations are represented in the following points:

- VTV mode should be considered as an effective alternative to PLV in the treatment of premature babies with RDS. The study found that VTV resulted in better outcomes for the babies in terms of oxygen saturation values for SPO2, and FiO2.
- Healthcare facilities that provide neonatal care should invest in VTV equipment and train their staff to use it effectively. The study demonstrated that VTV is a safe and effective mode of ventilation for premature babies with RDS, and its use may lead to improved outcomes.
- Healthcare providers should consider the potential benefits and risks of each ventilation mode and individualize their approach based on the patient's condition and clinical context.
- Healthcare providers who care for premature babies with RDS should consider using volume-targeted ventilation mode as an alternative to traditional pressure limited ventilation mode.

- Ventilator manufacturers can assist clinicians and researchers by making more detailed information available about how their VTV algorithms work. Additionally, manufacturers can assist the infants and their clinicians by incorporating evidence-based improvements to their VTV algorithms to current and new ventilators.
- Further research is needed to compare the effects of volume-targeted ventilation mode and traditional pressure-limited ventilation mode on another clinical outcomes of premature babies with respiratory distress syndrome in other settings.
- Further research is needed to determine the long-term effects of VTV on premature babies with RDS. While the study showed that VTV was effective in the short-term, more research is needed to determine if its use has any long-term effects on the development and health of premature babies.
- The study highlights the importance of conducting randomized controlled trials to compare different modes of ventilation in neonatal care. Further studies in this area can help to improve the quality of care provided to premature babies with RDS and other respiratory conditions.

List of Abbreviations

Abbreviation	Meaning
A/C	Assist/Control Ventilation
ARDS	Acute Respiratory Distress Syndrome
BP	Blood Pressure
BPD	Bronchopulmonary Dysplasia
BPM	Breaths Per Minute
cm	Centimetre
DIC	Disseminated Intravascular Coagulation
ELBW	Extremely Low Birth Weight
etc.	Et Cetera
FiO_2	Fraction of Inspired Oxygen
HR	Heart Rate
I:E ratio	Inspiratory to Expiratory ratio
ID number	Identity Document number
IRB	Institutional Review Board
IVH	Intraventricular Hemorrhage
Kg	Kilogram
LV	Left Ventricular
MEDLINE	Medical Literature Analysis and Retrieval System Online
MOH	Ministry of Health
MV	Mechanical Ventilation
NICU	Neonatal Intensive Care Unit
NRDS	Neonatal Respiratory Distress Syndrome
PBF	Pulmonary blood flow
PC	Pressure Control
PEEP	Positive End-Expiratory Pressure
PEmax	Maximal Expiratory Pressure

Ph	Power of Hydrogen
PImax	Maximal Inspiratory Pressure
PIP	Peak Inspiratory Pressure
PLV	Pressure-Limited Ventilation
PS	Pressure-Support
PubMed	Public/Publisher MEDLINE
PVL	Periventricular Leukomalacia
PVR	pulmonary vascular resistance
PVR	Pulmonary vascular resistance
RCTs	Randomized Controlled Trials
RDS	Respiratory Distress Syndrome
ROP	Retinopathy of Prematurity
RR	Respiratory Rate
RV	Right Ventricular
SIMV	Synchronized Intermittent Mandatory Ventilation
Spo2	Oxygen Saturation
SPSS	Statistical Package for the Social Sciences
TAA	Thoracoabdominal Asynchrony
VT	Tidal Volume
VTV	Volume-Targeted Ventilation
WHO	World Health Organization
WOB	Work Of Breathing

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Appendices

Appendix A

Study Tool

An-Najah National University
Faculty of Graduate Studies
Master of Critical Care Nursing

Questionnaire about:

COMPARING THE EFFECTS OF VOLUME-TARGETED VENTILATION MODE AND TRADITIONAL PRESSURE-LIMITED VENTILATION MODE ON THE CLINICAL OUTCOMES OF PREMATURE BABIES WITH RESPIRATORY DISTRESS SYNDROME. A CONTROLLED RANDOMIZED STUDY

Prepared by:

Reem Ataya

Supervised by:

Dr. Aidah Alkaissi

Section 1: Patient's information.

1) **Patient name or ID number:** …….

2) **Gender:**
   - □ Male.
   - □ Female.

3) **Gestational age (weeks):**
   - □ 29 weeks.
   - □ 30 weeks.
   - □ 31 weeks.
   - □ 32 weeks.
   - □ 33 weeks.
   - □ 34 weeks.
   - □ 35 weeks.
   - □ 36 weeks.

4) **Current age (days):**
   - □ From 0-7 days.
   - □ From 8-14 days.
   - □ From 15-21 days.
   - □ From 22-28 days.

5) **Birth Weight (kg):**
   - □ From 1 to 1.5 Kg.
   - □ From 1.51 to 2.5 Kg.
   - □ From 2.51 to 3.5 Kg.
   - □ More than 3.5 kg.

6) **Current weight (kg):**
   - □ From 1 to 1.5 Kg.
   - □ From 1.51 to 2.5 Kg.
   - □ From 2.51 to 3.5 Kg.
   - □ More than 3.5 kg.

7) Type of delivery:

- Normal vaginal delivery.
- Cesarian section.

8) Patient on:

- VTV
- PLV

Section 2: Clinical Outcomes.

It will be evaluated every 3 hours during first 24 hours.

Item	1st three hours	2nd three hours	3rd three hours	4th three hours	5th three hours	6th three hours	7th three hours	8th three hours
9) Blood Pressure (BP)								
10) Respiratory rate (RR)								
11) Heart rate (HR)								
12) Oxygen saturation (Spo2)								
13) Tidal volumes								
14) FiO2								

Section 3: Length of management.

15) Length of intubation duration during staying at NICU:

……..

16) Oxygen therapy duration during staying at NICU:

…….…….

Section 4: Complications.

Item	Present	Absent
17) Pneumothorax.		
18) Surfactant.		
19) Mortality before discharge		
20) Others (intra ventricular haemorrhage (IVH))		

Appendix B

MoH Approval Letter

State of Palestine
Ministry of Health
General Directorate of Education in
Health and Scientific Research

دولة فلسطين
وزارة الصحة
الإدارة العامة للتعليم الصحي
والبحث العلمي

الرقم: عمم/٥١٤٠/٢٠٢١
التاريخ: ٢٠٢١/١١/٢٣

Ref.: .....
Date:.....

الأخ مدير عام الادارة العامة للمستشفيات المحترم،،،

تحية واحترام،،،

الموضـــوع: تسهيل مهمة بحث

يرجى التكرم بتسهيل مهمة الطالبة: **ريم زياد قاسم عطايه، تخصص ماجستير تمريض العناية المكثفة– جامعة النجاح**، لعمل بحث الماجستير بعنوان:

"مقارنة آثار وضع التهوية المستهدفة بالحجم ووضع التهوية التقليدية المحدودة بالضغط على النتائج السريرية للأطفال الخدج المصابين بمتلازمة الضائقة التنفسية، دراسة عشوائية محكومة"

مع العلم أن مشرفة الدراسة: د. عائدة القيسي، حيث ستقوم الطالبة بجمع معلومات عن طريق تعبئة استبانة من ملفات المرضى في أقسام العناية المكثفة، **دون الحصول على المعلومات التعريفية للمرضى وتحت طائلة المسؤولية**، وذلك في:

- **مستشفى جنين**

على ان يتم الالتزام بجميع تعليمات واجراءات الوقاية والسلامة الصادرة عن وزارة الصحة بخصوص جائحة كورونا، وتحت طائلة المسؤولية.

على ان يتم تزويد الوزارة بنسخة PDF من نتائج البحث، التعهد بعدم النشر.

مع الاحترام،،،

د. عبد الله القواسمي
مدير التعليم الصحي والبحث العلمي

نسخة: منسقة برنامج ماجستير تمريض التخدير المحترمة/ جامعة النجاح

P.O .Box: 14
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ص.ب. 14
تلفاكس: 09-2333901

Appendix C

IRB Approval Letter

An-Najah National University
Faculty of Medicine & Health Sciences
Institutional Review Board

جامعة النجاح الوطنية
كلية الطب وعلوم الصحة
لجنة اخلاقيات البحث العلمي

Ref: Mas.. Nov. *2021/18*

IRB Approval Letter

Title of Research:
Comparing the effects of volume-targeted ventilation mode and traditional pressure-limited ventilation mode on the clinical outcomes of premature babies with respiratory distress syndrome. A controlled randomized study.

Submitted by:
Reem Ataya.

Supervisor:
Aidah Alkaissi

Approved:
14 th Nov. 2021

Your Study Title **"Comparing the effects of volume-targeted ventilation mode and traditional pressure-limited ventilation mode on the clinical outcomes of premature babies with respiratory distress syndrome. A controlled randomized study.."** reviewed by An-Najah National University IRB committee and was approved on 14th Nov.2021

Hasan Fitian, MD
IRB Committee Chairman

IRB

Nablus - P.O Box :7 or 707 | Tel (970) (09) 2342902/4/7/8/14 | Faximile (970) (09) 2342910| E-mail : hgs@najah.edu

Appendix D

Tables of Study

Table D1

Comparisons between VTV group and PLV group regarding the Complications (N=80)

Complications	Group		Total (N=80)	P-value*
	VTV (N=40)	PLV (N=40)		
Pneumothorax	2(5%)	3(7.5%)	5(6.3%)	0.644
Surfactant	4(10%)	5(12.5%)	9(11.3%)	0.723
Mortality before discharge	3(7.5%)	8(20%)	11(13.8%)	0.105
Other (IV-haemorrhage)	1(2.5%)	3(7.5%)	4(5%)	0.305

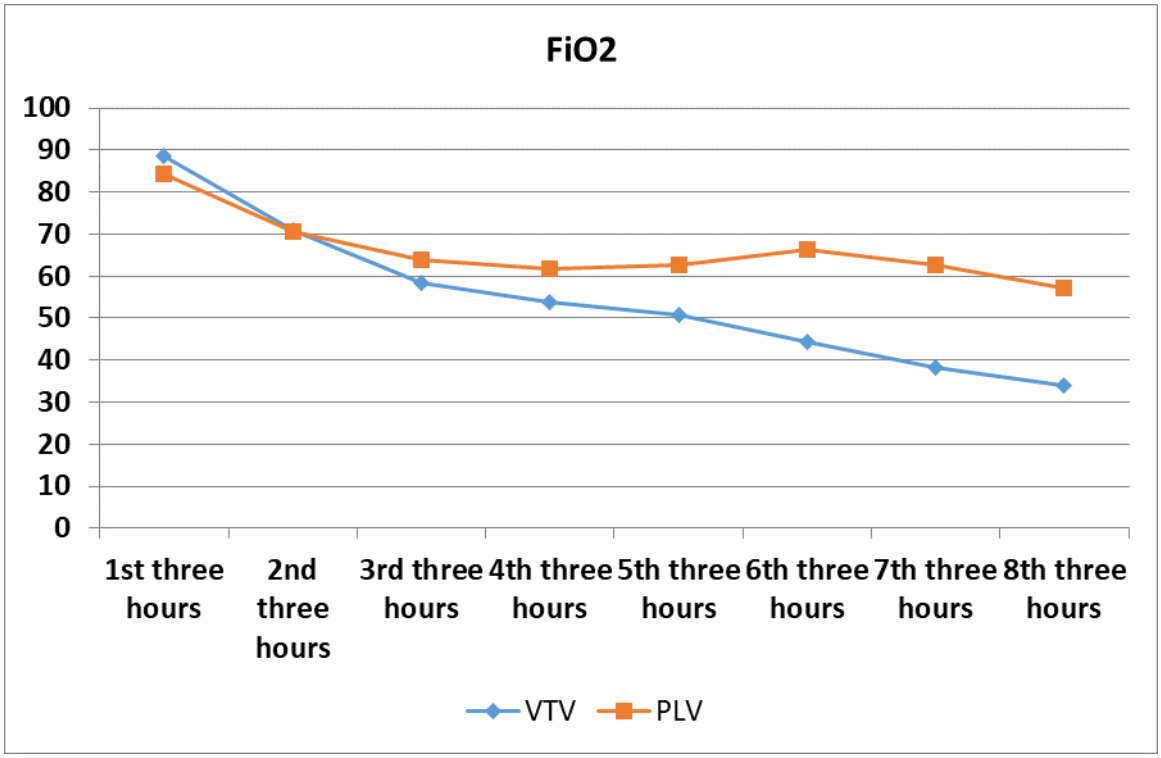
The P-values are related to the Chi-square test of independence and the numbers in the table represent N (%).

Appendix E

Figurers of Study

Figure E1

Comparisons between VTV group and PLV group regarding the FiO2 (N=80)



جـامعـــة النجاح الوطنية
كليـــة الدراســـات العليـــا

مقارنة آثار وضع التهوية المستهدفة بالحجم ووضع التهوية التقليدية المحدودة بالضغط على النتائج السريرية للأطفال الخدج المصابين بمتلازمة الضائقة التنفسية. دراسة عشوائية محوكمة

إعداد
ريم عطايا

إشراف
د. عايدة القيسي

قدمت هذه الرسالة استكمالا لمتطلبات الحصول على درجه الماجستير في تمريض العناية المكثفة، من كلية الدراسات العليا، في جامعة النجاح الوطنية، نابلس– فلسطين.

2023

مقارنة آثار وضع التهوية المستهدفة بالحجم ووضع التهوية التقليدي المحدود الضغط على الأطفال حديثي الولادة المصابين بمتلازمة الضائقة التنفسية.

دراسة عشوائية محوكمة

اعداد

ريم عطايا

إشراف

د. عايدة القيسي

الملخص

تحدث متلازمة الضائقة التنفسية (RDS) عندما لا تكون رئتي الأطفال الخدج مكتملة النمو وتفتقر إلى الفاعل بالسطح اللازم لإبقاء الأكياس الهوائية مفتوحة. تطورت أنماط مختلفة من التهوية لتقليل تلف الرئة للرضيع المبتسر والتحكم في كمية الهواء التي تدخل الرئتين مع كل تضخم. أكثر الأوضاع شيوعًا هي التهوية التقليدية المحدودة الضغط (PLV) والضغط الجديد الموجه لحجم الصوت (VTV).

تهدف هذه الدراسة لمقارنة تأثير VTV وPLV على النتائج السريرية BP, RR, HR, SaO2, Tidal volumes, FiO2 ومدة التنبيب، ومدة العلاج بالأكسجين والمضاعفات المترتبة على الأطفال الخدج الذين يعانون من RDS في مستشفى جنين الحكومي.

استخدمت الدراسة تصميم تجربة معشاة ذات شواهد. تتكون العينة من 80 طفل خداج، تم توزيع 40 منهم بشكل عشوائي على المجموعة التجريبية (VTV) و40 إلى المجموعة الضابطة (PVL). تم جمع البيانات باستخدام ورقة بيانات المريض.

بلغ العدد الإجمالي للمشاركين الذكور 42 (27 VTV و15 PLV)، بينما كان العدد الإجمالي للإناث 38 (13 VTV و25 PLV). تراوح عمر الحمل من 29 إلى 36 أسبوعًا. في هذه الدراسة كان 32.5٪ من مجموع المشاركين في الفئة العمرية ما بين 0–7 أيام، بينما 11.3٪ كانوا في الفئة العمرية من 22–24 يومًا. كان أعلى وزن عند الولادة من 1.51 إلى 2.5 كجم (46.3٪)، بينما كان أقل وزن عند الولادة أكثر من 3.5 كجم (1.3٪). أكبر عدد من المشاركين تراوحت أوزانهم ما بين 1.51 إلى 2.5 كجم، في حين شكل أولئك الذين يزيد وزنهم عن 3.5 كجم أقل عدد من المشاركين. حوالي 37.5 ٪ من المشاركات ولدن عن طريق الولادة الطبيعية المهبلية، في حين أن 62.5 ٪ من المشاركات ولدن عن طريق الولادة القيصرية. كان متوسط Spo2 في VTV (المتوسط = 97.7) بإجمالي 24 ساعة أعلى بكثير من المتوسط في PLV (المتوسط = 95.86). توجد فروق ذات دلالة إحصائية بين مجموعة VTV ومجموعة PLV في FiO2 في سادس وسابع وثامن 3 ساعات. عدد المرضى المتوفين في PLV هو 8 (20٪)، وهو أعلى من (P = 0.105) (7.5%) 3 VTV، ومع ذلك لم يكن هناك فرق ذا دلالة احصائية ولكن كان مناسبًا سريريًا.

أظهر وضع VTV قيمًا محسّنة لتشبع الأكسجين لـ SPO2 وFiO2 مقارنة بوضع PLV، وأظهرت النتائج أن عدد المرضى المتوفين في مجموعة PLV أعلى منه في VTV، ومع ذلك لم يكن هناك فرق ذا دلالة احصائية، ولكن ذو صلة سريريًا. لا يوجد دليل على زيادة أي نتائج غير مواتية مرتبطة باستخدام VTV مقارنة بـ PLV.

الكلمات المفتاحية: VTV، PLV، حديثي الولادة، متلازمة الضائقة التنفسية، فلسطين.