

**THE EFFECT OF POSTURE ON OXYGENATION, VITAL SIGNS
AND DURATION OF WEANING DURING WEAN OFF
MECHANICAL VENTILATOR IN PRETERM INFANTS**



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2007**

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THE EFFECT OF POSTURE ON OXYGENATION, VITAL SIGNS AND DURATION OF WEANING DURING WEAN OFF MECHANICAL VENTILATOR IN PRETERM INFANTS.

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ABSTRACT

The purpose of this quasi-experimental research was to compare the effects of side lying and regular positions on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off mechanical ventilator. The sample was 46 preterm infants (23 infants in the control group and 23 infants in the experimental group) who had been admitted in Neonatal Intensive Care Unit (NICU) Phranakornsri Ayutthaya Hospital and were selected according to the inclusion criteria. Data of control group were obtained from retrospective chart review and the data of experimental group were collected by posing the infant in the side lying position from April to November 2006. Statistical analyses used were T-test independent and repeated measure of ANOVA

The results revealed that the mean oxygen saturation and heart rate of preterm infants with side lying position was not significantly different from the regular position during weaning off mechanical ventilator ($p > .05$). Mean respiratory rate of the preterm infants with side lying position was significantly higher than regular position ($p < .05$) and duration of weaning in the preterm infants with side lying position was significantly shorter than regular position ($p < .05$). However, the preterm infants with side lying position had more stabilized oxygen saturation and heart rate than those in the regular position.

These findings suggest that nurses in the NICU should put preterm infants in side lying position during weaning off mechanical ventilator for stabilized oxygen saturation, heart rate and decreased duration of weaning off mechanical ventilator.

KEY WORD: PRETERM INFANTS, WEANING, MECHANICAL VENTILATOR, POSITION, POSTURE

64 P.

ผลของการจัดท่านอนทารกต่อค่าความอิ่มตัวของออกซิเจน สัญญาณชีพ และระยะเวลาในการหย่าเครื่องช่วยหายใจในทารกเกิดก่อนกำหนดขณะหย่าเครื่องช่วยหายใจ (THE EFFECT OF POSTURE ON OXYGENATION, VITAL SIGNS AND DURATION OF WEANING DURING WEAN OFF MECHANICAL VENTILATOR IN PRETERM INFANTS)

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บทคัดย่อ

การศึกษาครั้งนี้เป็นการวิจัยกึ่งทดลอง เพื่อเปรียบเทียบผลของท่านอนตะแคงและท่านอนปกติต่อค่าความอิ่มตัวของออกซิเจน อัตราการเดินของหัวใจ อัตราการหายใจ และระยะเวลาในการหย่าเครื่องช่วยหายใจในทารกเกิดก่อนกำหนดขณะหย่าเครื่องช่วยหายใจ กลุ่มตัวอย่างเป็นทารกเกิดก่อนกำหนดที่มีอายุครรภ์น้อยกว่า 37 สัปดาห์อยู่ในระหว่างหย่าเครื่องช่วยหายใจ จำนวน 46 คน (กลุ่มควบคุม 23 คน และกลุ่มทดลอง 23 คน) ในหออภิบาลทารกแรกเกิด (NICU) โรงพยาบาลพระนครศรีอยุธยา คัดเลือกทารกตามเกณฑ์ที่กำหนด เก็บข้อมูลในกลุ่มควบคุมจากการทบทวนเวชระเบียนในรอบปีที่ผ่านมา และเก็บข้อมูลทารกในกลุ่มทดลอง ที่ได้รับการจัดท่านอนตะแคง ตั้งแต่เดือน เมษายน ถึง เดือนพฤศจิกายน 2549 วิเคราะห์ข้อมูลโดยใช้สถิติ T-test independent และ Repeated measure of ANOVA

ผลการศึกษาพบว่า ทารกเกิดก่อนกำหนดที่ได้รับการจัดท่านอนตะแคงขณะหย่าเครื่องช่วยหายใจมีค่าเฉลี่ยของความอิ่มตัวของออกซิเจน และอัตราการเดินของหัวใจ ไม่แตกต่างจากทารกท่านอนปกติอย่างมีนัยสำคัญทางสถิติ ($p > .05$) แต่อัตราการหายใจของทารกกลุ่มท่านอนตะแคงสูงกว่าท่านอนปกติอย่างมีนัยสำคัญทางสถิติ ($p < .05$) และระยะเวลาในการหย่าเครื่องช่วยหายใจของทารกที่ได้รับการจัดท่านอนตะแคงน้อยกว่าทารกในท่านอนปกติอย่างมีนัยสำคัญทางสถิติ ($p < .05$) อย่างไรก็ตามทารกที่ได้รับการจัดท่านอนตะแคงจะมีค่าเฉลี่ยของความอิ่มตัวของออกซิเจน และอัตราการเดินของหัวใจที่คงที่กว่าทารกกลุ่มท่านอนปกติ

จากการศึกษาครั้งนี้มีข้อเสนอแนะให้พยาบาลในหน่วยงาน NICU ควรจัดท่านอนตะแคงให้ทารกที่ใช้เครื่องช่วยหายใจ และกำลังหย่าเครื่องช่วยหายใจ เพื่อส่งเสริมความคงที่ของค่าความอิ่มตัวของออกซิเจน และอัตราการเดินของหัวใจ ส่งผลให้ลดระยะเวลาในการหย่าเครื่องช่วยหายใจได้

CONTENTS

	Page
ACKNOWLEDGEMENTS	iii
ABSTRACT (ENGLISH)	iv
ABSTRACT (THAI)	v
LIST OF TABLES	viii
LIST OF FIGURES	x
CHAPTER	
I INTRODUCTION	
Background and Significance of the Study	1
Research Question	4
Purpose of the Study	4
Hypotheses	4
Conceptual Framework	4
Scope of the Study	6
Definition of Terms	6
Expected Outcomes/ Benefits	8
II LITERATURE REVIEW	
Preterm infants with mechanical ventilator	9
Weaning mechanical ventilation	11
Als' s synactive theory	14
Positioning and effect of position in preterm infant on mechanical ventilator and weaning off mechanical ventilator	15

CONTENTS (CONTINUED)

	Page
III METHODOLOGY	
Research Design	19
Population and Sampling	19
Setting	21
Instruments	23
Data Collection	24
Protection of Human Subjects	28
Data Analysis	28
IV RESULTS	29
V DISCUSSION	43
VI CONCLUSION	
Summary of the Study	47
Implications and Recommendations	48
Limitations of the Study	48
REFERENCES	49
APPENDIX	55
BIOGRAPHY	64

LIST OF TABLES

Table	Page
1. Preterm infants demographics	30
2. The result of t- test analysis with mean oxygen saturation during weaning process	32
3. Repeated measure of analysis of variance of mean oxygen saturation during weaning process of each group (regular position and side lying position)	33
4. Post Hoc analysis of mean oxygen saturation in the preterm infants with regular position during weaning process	34
5. The result of t- test analysis with mean of heart rate during weaning process	34
6. Repeated measure of analysis of variance in the mean heart rate during weaning process of each group (regular position and side lying position)	35
7. Post Hoc analysis of mean heart rate in the preterm infants with regular position during weaning process	36
8. The result of t- test analysis with mean of respiratory rate during weaning process	37
9. Repeated measure of analysis of variance of the mean respiratory rate during weaning process of each group (regular position and side lying position)	38
10. Post Hoc analysis of mean respiratory rate in the preterm infants with regular position during weaning process	38
11. Post Hoc analysis of mean respiratory rate in the preterm infants with side lying position during weaning process	39
12. The result of t- test analysis with mean of the duration of weaning process	40
13. Repeated measure of analysis of variance of the mean duration of weaning process of each group (regular position and side lying position)	41
14. Post Hoc analysis of the mean duration of weaning process in the preterm infants with regular position	41

LIST OF TABLES (CONTINUED)

Table	Page
15. Post Hoc analysis of the mean duration of weaning process in the preterm infants with side lying position	42



LIST OF FIGURES

Figure	Page
1. Conceptual framework of the study	6
2. Posture in side lying position	7
3. The step of making “Nest” in this study	23
4. Diagram of data collection process in side lying position	27
5. Compared mean oxygen saturation of preterm infants during weaning process between regular position and side lying position	33
6. Compared mean heart rate of preterm infants during weaning process between regular position and side lying position	35
7. Compared mean respiratory rate of preterm infants during weaning process between regular position and side lying position	37
8. Compared mean of duration of weaning process between regular position and side lying position	40

CHAPTER I

INTRODUCTION

Background and Significance of the Study

Currently the progress of the medical science and high technology resulted in increasing survival of high risk infants and decreasing of morbidity and mortality rate. Generally, most of high risk infants are born prematurely with the respiratory distress syndrome (Jirapaet & Jirapaet, 2002), which is the result of incomplete lung surfactant and structure (Huaphaophan, 1999). Normally, these premature infants must be taken care in the Neonatal Intensive Care Unit (NICU), used the mechanical ventilators and observed closely to reduce morbidity and mortality. It has found that the premature infants with prolonged mechanical ventilator often suffered many complications such as bronchopulmonary dysplasia (BPD), retinopathy of prematurity (ROP), intraventricular hemorrhage (IVH) or pneumothorax (Jirapaet, 1997; Huaphaophan, 1999).

Therefore, the issue of weaning off mechanical ventilator is necessary to take into account, the earlier of weaning the lesser of complications. The criteria for consideration to wean mechanical ventilator composed of gestational age, weight, status of disease, breathing pattern and blood gas (FiO_2 0.4-0.35, $PaCO_2 \leq 40$ mmHg, $PaO_2 \geq 60$ mmHg) with PEEP < 5 cmH₂O (Chantharojsiri, 2000; Epsein, 2000; Jirapaet, 1997; Jirapaet & Jirapaet, 2002; Sinha & Donn, 2002; Thaithumyanon, 2001).

Nurses who took care of these infants have a major role in monitoring the weaning process smoothly until the infants will be extubated. Effective nursing care for weaning off the mechanical ventilator consists of suctioning air way; monitoring body temperature for hypothermia or hyperthermia; positioning properly; monitoring oxygen saturation, respiratory rate and heart rate as well as assessing the clinical signs and symptoms of infants. One of the processes for weaning from the mechanical ventilator is to increase oxygen saturation and maintain level of oxygen in circulation.

This can be done by positioning to promote the drainage of secretion by gravity with easily to suction resulted in promoting lung expansion and the effective gas exchange.

In addition, proper position promotes the physiological function of the infant according to the synactive theory (Als, 1982; 1986) which composed of autonomic system, motor system, state organization system, attention and interaction system and self regulation system. In normal infants these systems will function integratively to balance subsystem state and reduce stress from stimuli to the autonomic system such as color changes, heart rate and respiratory rate while increasing oxygen saturation or motor system development expressed in the gestures of infants i.e. finger splays, fisting, and facial grimaces. The important advantages of proper positioning for preterm infants are exhibited in oxygen saturation due to gravity with blood flow and plural pressure gradient which will be a cause for the improvement of ventilation-perfusion (Khamsriboos, 2005; Hinchliff, Montague & Watson, 1996; Sootornlokhanakul, 2000) and promote the effective care of infants on mechanical ventilators.

From the review of literature, there was a systematic review (Balagure, Escribano & Roque, 2003) of 10 research studies dealing with positioning in the preterm infants received mechanical ventilator since 1990-2002. It was found that the prone position had a small significant benefit to increase oxygen saturation. Other positions have not enough evidences to support benefit.

Besides the systematic review there were some single studies related to positioning in infant such as side lying position, supine with flexion or supine with head tilt; significantly affect oxygenation and body temperature (Dimitriou, Greenough, Pink, McGhee, Hickey & Rofferty, 2001; Yottiem, Tilokskulchai, Vichitsukon & Kolatat, 2004) According to the findings, the side lying position increases oxygen saturation second to the prone position (Khamsriboos, 2005). These findings are congruence with the study of Yottiem et al. (2004) which found that the side lying position could significantly increase oxygen saturation in comparison with the regular supine position with flexion ($p < .05$) while promoting more upper than lower lung expansion (Heaf, Helms, Gordon & Turner, 1983). Moreover, this position is suitable for infants with pathology of the lung as it promotes the gravitational drainage of secretions in order to reduce upper respiratory obstruction (Jirapaet,

Kayoonvichien & Jirapaet, 1994) and control body temperature more effectively than the supine position (Yottiem, et al., 2004). Moreover, the side lying position creates symmetry of trunk and head that is similar to the fetal position which comforts infants and helps them control themselves as reflected in calm behavior (Khamsriboos, 2005; Thanacharoenpipat, 2000).

However, the position for preterm infants receiving mechanical ventilator still have some risks and limitations. Some positions such as the prone position due to increase high volume in the lungs and oxygen saturation, it may have risk to accidental extubation or decatheterization than other positions (Chang, Anderson, Dowling & Lin, 2002; Numa, Hammer & Newth, 1997). Therefore the most position that nurses routinely manage for infants is the supine position which may result in stiffness of joint (Phunnahitanon, 2005) and rather poor gas exchange (Chang, et al, 2002; McEvoy, Mendoza, Bowling, Hewlett, Sardesai & Durand, 1997) or air way obstruction (Jirapaet & Khamsriboos, 1991; Jirapaet, et al.,1994).

Most of studies about positioning in preterm infants are related to infants receiving mechanical ventilator, only few studies related to weaning off the mechanical ventilator. The study of Antunes, Rugolo and Crocci (2003) compared oxygen saturation, heart rate and respiratory rate in prone and supine positions of preterm infants being weaned off the mechanical ventilator and found no significant difference between the prone and supine positions. However, oxygen desaturation episodes were more frequent in supine position ($p = .009$).

Few studies, however, studied the effects of different positions on physiological parameters during the process of weaning off mechanical ventilator. Therefore the researcher is interested in studying the effect of posture on oxygenation, heart rate, respiratory rate and duration of weaning during the weaning process in preterm infants, the results from this study can be used as a guideline for the nursing care of preterm infants during the weaning process to reduce complications and expenses during hospitalization.

Research Question

What are the effects of the side lying and regular positions on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off mechanical ventilator?

Purpose of the study

To compare the effects of side lying and regular positions on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off mechanical ventilator.

Hypotheses

1. Mean oxygen saturation in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.
2. Mean heart rates in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.
3. Mean respiratory rates in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.
4. The duration of weaning in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

Conceptual Framework

The conceptual framework that guided this study is the concept of Als' synactive theory (Als, 1982; 1986; Als, Butler, Kosta & McAnulty, 2005) which explained changes in physiologic and behavioral responses of preterm infants to stimulation and interaction with surroundings in terms of the following 5 subsystems: the autonomic system, the motor system, the state organization system, the attention / interaction systems and the self-regulation system. 1) The autonomic system is baseline functioning which represent infant's behavior in the pattern of respiration (regular respiration, respiratory pauses or tachypnea), color changes (pink, mottling, cyanosis and grayness), and visceral signals such as bowel movements, gagging and hiccoughing. 2) The motor system is seen in the posture, tone and movements of the organism gestured such as hypertonic (airplane; finger splays; sitting on air) or

hypotonic (flaccid). 3) The state organizational system is seen in the range of state of consciousness (from sleep to awake and full aroused with crying), depend on the pattern of state transitions. 4) The attention and interaction system is explained in the infant's ability to take in adapt and present in cognitive and social emotional information around them, and to come to an alert, attentive state. Finally, the self-regulatory system is infant's behavior to explain the strategies of organism to use to maintain balanced and integrated of subsystem. When the infants can adapt to environmental change by themselves, behavioral pattern will be normal. If they can't adapt to environmental change the behavioral pattern will be abnormal as color change, pattern respiratory change or facial grimace.

Therefore, caregiver should understand and evaluate infants in these subsystems. Als' synactive theory (1982, 1986) can help caregiver to understand the infants in order to adjust caring, to support the infants and respond to their need. In the nursing care, the autonomic system is the primary focus and useful to assess them. To achieve the objectives of this research, the researcher aimed to study the effects of positions for preterm infants during weaning off mechanical ventilator by using the autonomic system assessment which evaluates basic physiologic signs such as oxygen saturation, heart rate and respiratory rate that must be stable and regular to support the reduction of the duration of time required for weaning off mechanical ventilator and successful extubation.

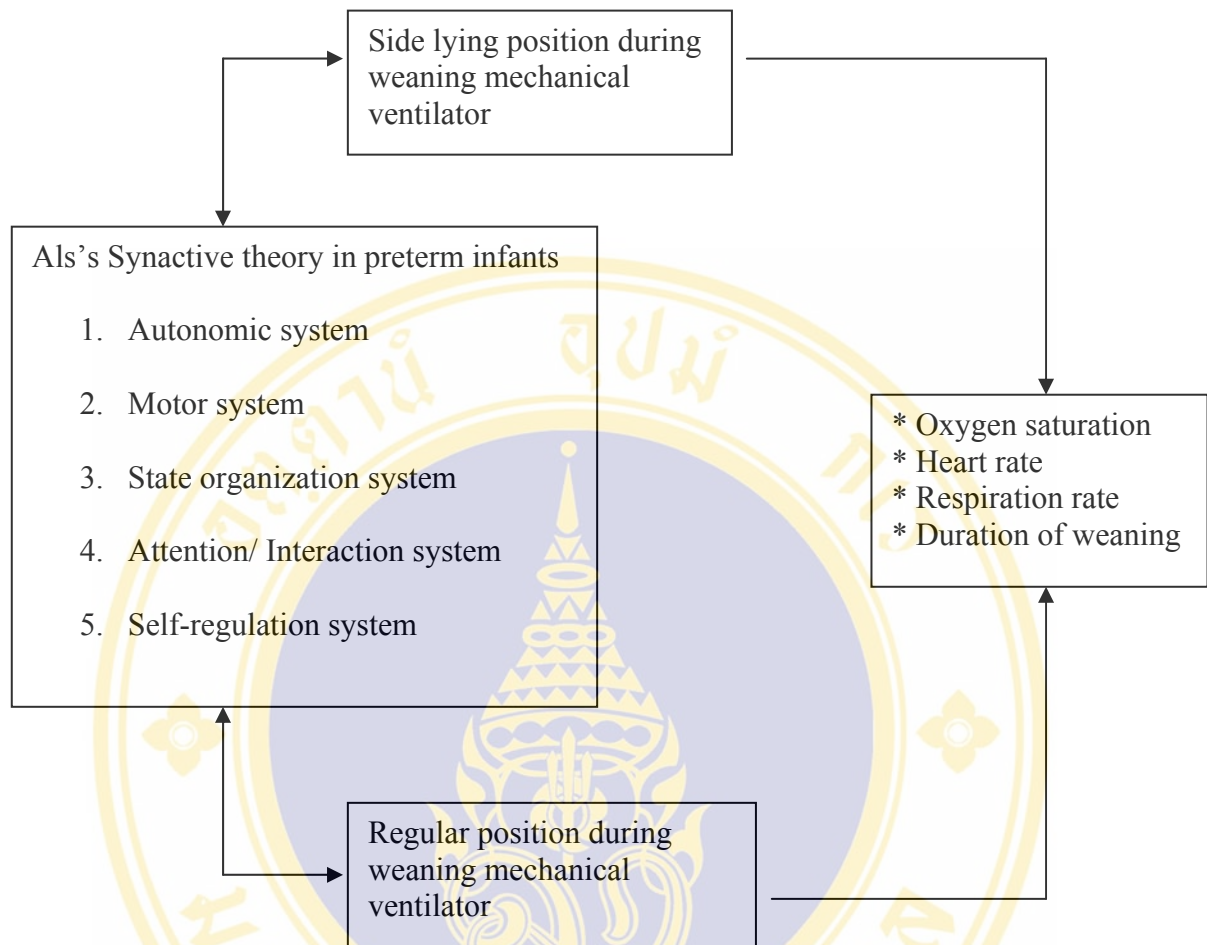


Figure 1: Conceptual framework of the study.

Scope of the Study

This research is a quasi-experimental design aimed to compare the effect of side lying and regular positions on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off mechanical ventilator in NICU at Phranakornsri Ayutthaya hospital from April to November 2006.

Definition of Terms

Posture referred to the position of infants either the regular position that the staff nurse provided to the infant or side lying position that the researcher provided to the infant.

Regular position referred to the position of preterm infants who were placed on the midline of a nest (the nest consisted of a rolled blanket that provided a

boundary for the infants) which has been routinely provided to the preterm infants by staff nurses in NICU during the process of weaning off mechanical ventilator. The positions which regularly provided including the supine, prone and side lying positions with the most common being the supine extended position.

Side lying position referred to the position of preterm infants who were placed on the midline of a nest (the nest consisted of a rolled blanket that provided a boundary for the infants and could be used as back support). The infants were put on their left or right side with the head slightly flexed and tilted in a neutral head-trunk alignment with flexing arms and cuddled forward at the shoulders, as were the hips and knees with a blanket rolled behind the head and trunk and between the legs (Monterosso, Kristjanson, Cole & Evans, 2002; Sweeney & Gutierrezl, 2002; Thanacharoenpipat, 2000; Yottiem, et al., 2004). Infants should be placed the head in an elevated tilt position of 15-30° (Jenni, Siebenthal, Wolf, Keel, Duc & Bucher, 1997). (Figure 2)



Figure 2: Posture in side lying position.

Oxygenation referred to oxygen saturation which is the percentage of hemoglobin available to bind oxygen (in plasma) (Schutz, 2001). The normal range of oxygen saturation in the preterm infants is 92 - 95 % (Carlo & Chatbourn, 1988; Jirapaet, 2002; Schutz, 2001; Sirirangkul & Sathawon, 2002; Sritippawan, 2005). Oxygen saturation is measured by pulse oximeter of Nellcor Puritan Bannett: N-550.

Vital signs in this study were defined as heart rate and respiratory rate

Heart rate referred to the number of heartbeats of the preterm infants per minute. The normal range of heart rate is 120-160 beats per minute of preterm infants. The heart rate is measured by Nellcor Puritan Bennett: N-550.

Respiratory rate referred to the number of the respiration of the preterm infants per minute; this normal rate is 40-60 beats per minute.

Duration of weaning referred to the time from the beginning of weaning process until successful weaning. The value will be recorded in number of hours and minutes.

Expected Outcomes/ Benefits

The results of this study will be able to use as a guideline for providing the proper position for preterm infants during the process of weaning off mechanical ventilator.

CHAPTER II

LITERATURE REVIEW

The purpose of this research study was to determine the effect of positioning on oxygenation, heart rate, respiration rate, and duration of weaning from mechanical ventilator in preterm infants. The researcher reviewed related literatures as follows:

- Preterm infants with mechanical ventilator
- Weaning mechanical ventilator
- Als' s synactive theory
- Positioning and effect of position in preterm infant on mechanical ventilator and weaning off mechanical ventilator

Preterm infants with mechanical ventilator

Respiratory system is a major problem of preterm infants because of immature functioning organ, particularly respiratory system, which is important on their life. So, mechanical ventilation is used in the treatment of neonatal pulmonary insufficiency. Mechanical ventilation has been steadily refined, resulting in the successful treatment of most fetal disease and improving survival rate from high risk neonate (Greenspan, Shaffer, Fox, & Spitzer, 2004). Treatment with assisted ventilation is applied commonly to newborns that have several different modes such as: CPAP (nasal, face mask or endotracheal CPAP), positive pressure ventilation (pressure, volume, & time-cycle limited), negative pressure ventilation, high-frequency, extracorporeal membrane oxygenation and liquid ventilation (Greenspan, et al., 2004; Yeo, 1998). All types of ventilator support serve the same function as assist in gas exchange to reduce lung insufficiency, and inability of the lung to exchange gas adequately. The ventilator support could reduce severity from common causes of preterm infants period such as respiratory distress syndrome (RDS), apnea of prematurity, Wilson-Mikity syndrome and pulmonary air leak syndrome (Chawalitthumrong, 1997; Jirapaet & Jirapaet, 2002).

Normally, the decision of initiation of assisted ventilation, that should be individualization for each baby. Factors to consider include: disease, natural history, birth weight, gestational age, postnatal age, chest radiographic appearance, progression clinical signs, and blood gas (PaO_2 between 45-70 mmHg, PaCO_2 45-60 mmHg or less, $\text{pH} > 7.25$). However, the general guideline for assisted ventilation must be interpreted and modified to provide optimal support for the individual infants (Jirapaet & Jirapaet, 2002; Szymankiewicz, Vidyasagar, & Gadzinowski, 2005; Truog & Golombek, 2005).

Mechanical ventilators used in NICU, have a lot of mode to support infants, who need ventilator. The using of each mode depends on individual or clinical type or disease of infants. Normally, mode of mechanical ventilation has about 4-5 modes as CMV, IMV, A/C, SIMV, and CPAP (Greenspan, et al., 2004; Jirapaet, 1997; Truog & Golombek, 2005) detailed as follows:

- Control Mandatory Ventilation (CMV mode), this mode is suitable for infants who can't spontaneous breathing or received sedative or paralyzed drug. In general, at early state this mode is preferable for infants.
- Intermittent Mandatory Ventilation (IMV mode), this mode is used for infants who can not trigger and spontaneous synchronize ventilator or have problem in respiratory system. In some ventilator CMV mode and IMV mode are the same.
- Assist – control (A/C mode), this mode is used for infant who can trigger medical ventilator, may be accompanied with CMV or IMV mode
- Synchronized Intermittent Mandatory Ventilation (SIMV mode), this mode is triggered mechanical ventilator by infant and spontaneous effort can be synchronized by mechanical ventilator. Generally this mode is used in the weaning period.
- Continuous Positive Airway Pressure (CPAP mode), is generally used after extubate to prevent reintubate tube and atelectasis.

Summary, the mechanical ventilation is used to help and ensure infant, maintain adequate gas exchange in the lung, maintain adequate oxygenation, remove carbon dioxide and assist infant for recovery. Weaning is the later process, when infant can have spontaneous breathing. The physician will make decision to weaning ventilator, base on clinical symptom of infants.

Weaning mechanical ventilator

Respiratory failure in the preterm infants needs to use assisted mechanical ventilation. The infant who has improved clinical condition from treatment and can have spontaneous breathing will be determined to discontinue mechanical ventilator or reduce in the level of ventilator support which refer to the term “weaning” (American College of Chest Physicians, 1993 cited in Kollef, et al, 1997; MacIntyre, 2001; Sinha & Donn, 2002). Therefore weaning is the process of discontinuing or withdrawing from mechanical ventilation, when the infant who use assisted ventilator can have spontaneous breathing or are resolved clinical problem. Decreasing the amount of ventilator support will be slowly and proportionally with clinical condition and blood gas infants.

Shinha and Donn (2002) proposed that practice guideline in the weaning process off mechanical ventilator as follows:

1. Assessment for weaning

General assessment infant to determine whether he/ she can be withdrawn from ventilator. This should consider associated components as follows:

1.1 Physiology of respiratory system of infants

Physiologic response for weaning to effective spontaneous breathing in dependent on a delicate balance between the loads imposed on the respiratory system and its capacity. The inability to tolerate extubation may be the result of poor effort, increase work of breathing and decrease inspiratory drive.

1.2 Blood gas of infants

The level of blood gas that could be considered to wean from mechanical ventilator is $\text{pH} > 7.25$, $\text{PaO}_2 > 45-70$ mmHg, and $\text{PaCO}_2 < 45-60$ mmHg (Jirapaet, 1997; Truog & Golombek, 2005).

1.3 Clinical condition of infant

In order to consider weaning, the clinical condition, especially physiologic status of infants, should be stable.

2. Weaning strategies

When the infant has clinically stabilized and accepted blood gas values, the ventilatory support must be decreased. The general principle of weaning should decrease the most potentially harmful at first parameter (Sinha & Donn,

2002).

The weaning strategies for ventilatory parameter is base on arterial blood gas results in describing e.g. weaning from conventional ventilation is extubated from low rate IMV, either directly to supplemental oxygen or Continuous Positive Airway Pressure (CPAP).

Shinha and Donn (2002) propose adjuncts of weaning include as 1) Continuous Positive Airway Pressure (CPAP), 2) pharmacological agent and 3) methylxanthines.

1) Continuous Positive Airway Pressure (CPAP). Using of CPAP in premature infants during postextubate tube and prevention of reintubate tube, apnea of prematurity, and primary treatment of respiratory distress syndrome with or without surfactant (Goldbart & Gozal, 2004).

2) Pharmacological agent. Corticosteroids may use in infants who increase risk for airway edema or obstruction e.g. the infants who have repeated or prolonged intubation. Furthermore, it is to prevent chronic lung disease in postnatal extubation.

3) Methylxanthines (Theophylline and Caffeine) have been used for long time. Because many study show advantages about increased central respiratory drive and increased respiratory muscle contractility and endurance.

Recovering from natural history of preterm disease and decision making in identifying the optimal time for extubated tube should be adjusted by physician. From assess different physiologic functions of the respiratory system, including effect of breathing and respiratory muscle endurance (Shinha & Donn, 2002; Yeo,1998).

3. Nursing care in the weaning process

The weaning process is the most important for preterm infant who received mechanical ventilator, because of infant who has prolong period of assist mechanical ventilation may be associated with the development of airway abnormalities such as subglottic stenosis, tracheomalacia (Davis & Rosenfeld, 2005) or complication as Bronchopulmonary Dysplasia (BPD), Retinopathy of Prematurity (ROP). So the weaning process should had short period for reduced complication or prevent abnormality development of infant. In nursing process of weaning ventilator should have 3 states as follows:

3.1 Before weaning period

In convalesce period that infants who on ventilator can have adjusted spontaneous breathing. The assessment of clinical sign of infants, whom improved blood gas, that can decrease in pressure, oxygen level and respiration rate of ventilator, and hemodynamic stable. Physician assesses to optimal time for weaning off ventilator. The nurse should be to assess and observe in clinical of infants who may be into the weaning process. This assessment should be in the protocol of weaning. Which, include oxygenation (oxygen saturation or blood gas) and ventilation (muscle of respiration, work of breathing, lung function).

3.2 During weaning period

This period is important in successful of weaning off mechanical ventilator. The staff nurse must bedside monitor, because clinical signs in weaning period may be quickly change. This monitoring is oxygenation, vital signs, tolerance during reduces level of ventilator and characteristic of respiratory of infants. Furthermore, this period nursing care include nutrition, comfortable position, prevent nasocomial infection, temperature and supporting parent (Yeo, 1998). When infants can spontaneous breathing and not require ventilator. Physician considers to extubation.

3.3 Post extubation period

Continuous Positive Airway Pressure (CPAP) is used for prevent complication (atelectasis and reintubate tube), so the staff nurse should bedside monitor as same as during weaning period. This period is high risk in reintubate tube or risk to easily lung collapse. Not provide oral feeding at fewer 4 hours (Jirapaet & Jirapaet, 2002; Thaitumyanon, 2001), prevent aspiration and decrease work of breathing.

The weaning process from mechanical ventilation of baby may be 'art and science' (Sinha & Donn, 2002). Short period intubate tube is one of the major goals of infants ventilatory management (Szymankiewicz, et al., 2005). In nursing care should be support physician treatment, in weaning by bedside. Nurse is first people who meet the infant's problem, so nursing care during weaning period is important as well as assists ventilator. The nurse can help by monitoring and observation infant's behavior, and can read infant's behavior by synactive theory.

Als' s synactive theory

Als (1982; 1986) described that synactive theory are functioning of systems in preterm infants comprised 5 subsystems. These are the autonomic system, the motor system, the state-organizational system, the attention and interaction system, and a self-regulatory balancing system. (Als, 1982; 1986; Als, et al., 2005).these systems are mutually supportive interplay with environment and the way infants communicate by their behavior. The details of 5 subsystems are as follows:

I. The autonomic system

The autonomic system is the primary focus of medical care and the physiological functioning base on survival of preterm infant. This system is accounted as the pattern of respiration, oxygenation, heart rate, color change, tremulousness and visceral signals such as bowel movements, gagging, hiccoughing.

The autonomic system is the first subsystem of preterm infants that must be controlled. When preterm infants interact with environment appropriately, coping responsiveness should be smooth movements and stable autonomic signs. If they have stress, they will display behavior such as color change as mottling, pallor, and cyanosis, oxygenation change, vital signs change as increase or decrease of heart rate, respiratory rate and blood pressure; visceral signals as gagging, sneezing, yawning and increase or decrease of bowel movements.

II. The motor system

The motor system is about muscle tone, such as posture movement and tone. When they have stress, they will show behavior such as: generalized hypotonia as flaccid, extension, or hyper-flexed, or specific movement patterns of the extremities, head, trunk, and face such as arching, finger splay, fisting, and grimace, and level of activity.

III. The state-organizational system

The state-organizational system is evident of the range of state of consciousness (from sleep state to arousal, awake, alert and crying), in the pattern of state transitions exhibited. In this system, infant stress presents behavior diffuse sleep state such as twitching, grimacing, glassy-eye, gaze aversion, panicked look, and irritability that is hard to console.

IV. The attention and interaction system

The attention and interaction system is exemplified in the organism's ability to come to an alert, attentive state and to use this state to take in cognitive and social emotional information from the environment and, in turn elicit and modify these inputs from the environment around them. When they can't orient or had stress, signs of stress in this system include stress of signals of the autonomic, motoric, and state-organizational systems.

V. The self – regulatory system

The self – regulatory system is associated with infant's ability to maintain balance, relatively stable and relaxed state of this system by him/ her-self. May be used of self consoling example sucking or hand to mouth maneuvers for soothing, or position is same in the womb. But infant's self-regulatory is not able adaptation, they may be display behavior such as color or respiratory pattern change, alteration in heart rate and respiration rate, abnormal body movement, irregular visceral signal (unable feeding), and restlessness.

Preterm infant, who required mechanical ventilation and plan to wean off ventilator must be maintained oxygen saturation and stabilize vital signs for this process to be success there are many factors that promote success of weaning ventilator such as medical, condition of infant and nursing care. One strategy of nursing care that improves oxygen saturation is positioning. Many research studied the relationship between positioning preterm infant were assisted or without ventilator about oxygenation, cardiovascular and energy expenditure suggest position have effect to which. Therefore, it is necessary to allow preterm infants in weaning to recover period from excessive procedures, have uninterrupted sleep to gain weight, and keep oxygen requirements to minimum level (Yeo, 1998).

Positioning and effect of position in preterm infants on mechanical ventilator and weaning off mechanical ventilator

The optimal goals of nursing care of preterm infants are to improve oxygenation, gain weight and reduce energy expenditure which ultimately improve quality of infant's life. The proper positioning is one of method in nursing care preterm infants, which helps to clam down the infant, reduce energy expenditure,

improve oxygenation and gain weight. Likewise, the proper position has affected on sleep characteristics in infants. It was studied by Goto, Maeda, Mirmiran and Ariagno (1999) about the relationship between positions (prone versus supine position) and sleep characteristics in preterm infants, and the duration of the first quiet sleep was significantly longer in the prone position which is congruent with the study of Change, Anderson and Lin (2002) who found that the preterm infants received mechanical ventilator in prone position had more quiet sleep than supine position significantly ($p < .001$). Many research studies recommend that proper position in preterm infants has promote oxygenation, sleep pattern, neuromuscular, and respiration during on ventilator or post-extubate tube, as follows:

In the systematic review by Balagure, Escribano and Roque (2003) in the Cochrane Database of Systematic Reviews, they included 10 trials in the analysis and found that most of samples in these trials were preterm infants, who have gestational age 23-36 weeks. The most of trials studied in preterm infants, who received mechanical ventilation with intermittent mandatory ventilation (IMV), but two trials study both IMV and continuous positive airway pressure (CPAP). The number of preterm infant in this review was 164 infant. Range of intervention period for positioning was mostly recorded about 2 minutes to 2 hours. The result of review revealed that the prone position improved a small significant oxygenation better than supine position (WMD 2.77%; 95% CI 1.17-4.36), and significant decrease in the pCO₂ (WMD -3.77 mmHg, 95% CI -6.65 to -8.89), while the other position did not have many studies to conclude whether or not prone position produces sustained benefits on pulmonary or other parameter.

Other than this systematic review, there are some researches studied the effect of position on breathing pattern, pulmonary function and heart rate, oxygenation or transcutaneous oxygen pressure or incident and type of apnea in preterm infants, who were post extubation period or recovered from respiratory disease (Lioy & Frank, 1988; Maynard, Bignall & Kitchen, 1999; McEvoy, et al., 1997; Wolfson, Greenspan, Deoras, Allen & Shaffer, 1992). They found that TcPO₂, PaO₂ increase in the prone position. There was studied by Maynard, Bignall and Kitchen (1999) and Wolfson, Greenspan, Deoras, Allen and Shaffer (1992) found that the prone position decreased asynchronous chest wall movements more than supine position. While, McEvoy,

Mendoza, Bowling, Hewlett, Sardesai and Durand (1997) found that the prone position improved oxygenation and decreased episodes of hypoxemia.

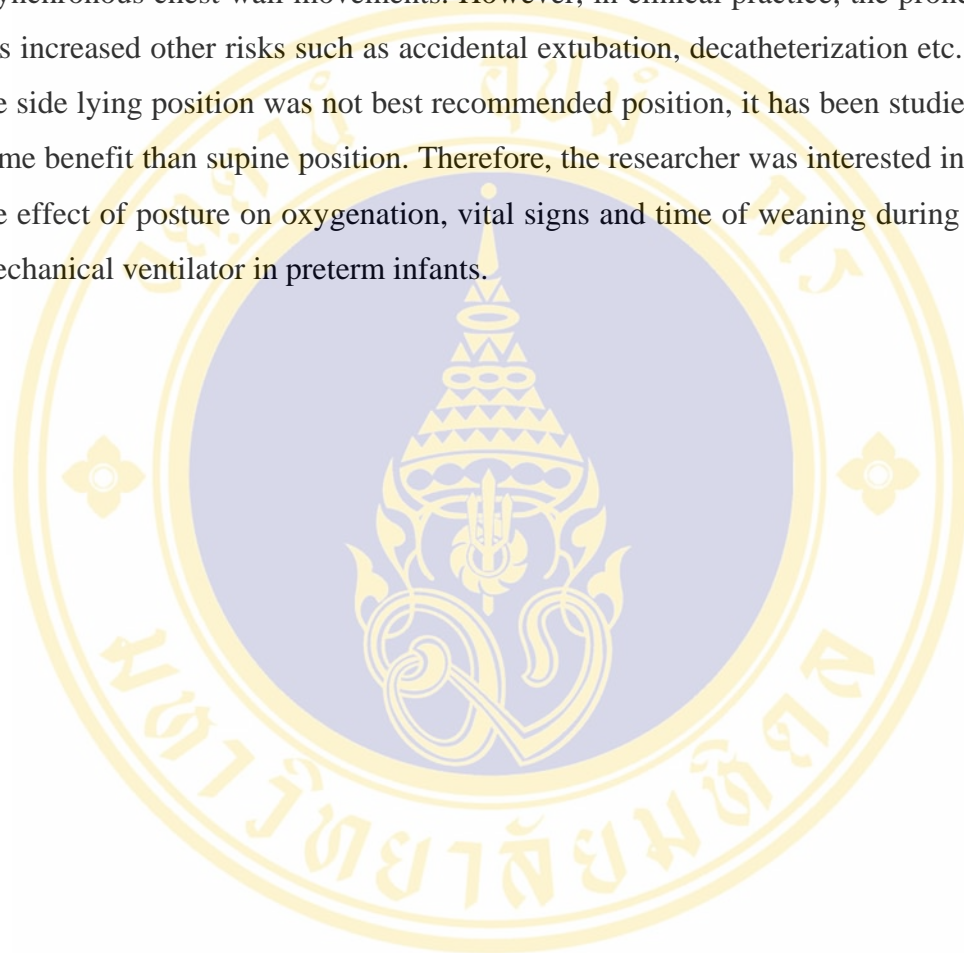
In addition, there were some studies investigated the relationship between position and the pattern of breathing; incidence, type and duration of clinical apnea in preterm infants who had clinical apnea and bradycardia. They found that supine position increased periodic breathing ($p = .015$) and apnea density significantly ($p = .01$). But no difference in respiratory rate or heart rate or incidence of the bradycardia and prolong apnea in both position (Heimler, Langlois, Hodel, Nelin, & Sasidharan, 1992). There was one study found more central and mixed apnea in supine than prone position significantly ($p = .025$, $p = .012$) (Kurlak, Ruggins & Stephenson, 1994).

Although many researches studied the outcome of positioning in oxygenation, pulmonary function, pattern of breathing, and incident of apnea of preterm infants on medical ventilator. However, there was little, if any, studied those parameters during post extubation period. Antunes, et al. (2003) studied the association between position and oxygen saturation (SaO_2), respiratory rate, heart rate, during the reduction period of the ventilator parameters during the weaning process and on the frequency of success or complications during that process. This research was studied between prone and supine position in preterm infants. The result found that there was no difference in respiratory rate, heart rate and transcutaneous oxygen saturation between prone and supine. However, oxygen desaturation episodes were more frequent in supine position ($p = .009$). In addition, ventilatory parameters decreased faster and reintubation was less than in the prone position (4% vs. 33%). They suggested that prone position was safe and beneficial procedure during the weaning off mechanical ventilator. The prone position may contribute to success weaning in preterm infants.

In Thailand, there was only one trial that studied positioning of preterm infants with assisted mechanical ventilation on oxygenation, heart rate, respiration rate, blood pressure and temperature by Yottiem, et al. (2004). They studied about regular position, supine with flexion and side lying in preterm infants who received assisted mechanical ventilation and found that position in preterm infants in a side lying position and supine with flexion position was resulted in significant higher mean oxygen saturation ($p = .000$) and mean skin temperature than regular position

($p = .002$). No different significance in heart rate, respiratory rate and blood pressure in either position was found.

From the review of literatures as mentioned above, the prone position is the best position for preterm infants, which improved oxygenation and decreased in asynchronous chest wall movements. However, in clinical practice, the prone position has increased other risks such as accidental extubation, decatheterization etc. although the side lying position was not best recommended position, it has been studied to have some benefit than supine position. Therefore, the researcher was interested in studying the effect of posture on oxygenation, vital signs and time of weaning during wean off mechanical ventilator in preterm infants.



CHAPTER III

METHODOLOGY

Research Design

This research is a quasi-experimental design aimed to compare the effects of a side lying position versus the regular position on oxygen saturation, heart rate, respiratory rate and duration of weaning during the process of weaning off mechanical ventilator.

Population and Sampling

Population

The population for this study consisted of preterm infants with gestational ages of < 37 weeks who were admitted in the Neonatal Intensive Care Unit (NICU) at Phranakornsri Ayutthaya Hospital. The sample of this study was purposively selected from the population with the following criteria:

Inclusion criteria:

1. The infants who required use of mechanical ventilator at least 48 hours from birth or within the first week after delivery.
2. The infants with no congenital anomalies.
3. The infants with no prohibitions or limitations for arranging side lying position such as umbilical catheters or ICD tubes.
4. The infants must have treatment plan for weaning off the mechanical ventilator.
5. Parents consent to participate in this study.

Exclusion criteria:

1. The infants with deteriorated symptoms when weaning off mechanical ventilator i.e. desaturation > 20% from the base line, breathing that requires the use of abdominal muscles or breathing with more retraction in correlation to the respiratory rates $\geq 60 \pm 10$ beats per minute and heart rate $\geq 160 \pm 10$ beats per minute.

2. The infants who require mechanical ventilator mode changes back to the initial or original mode.

Sampling

The sample size was calculated base on the study of Yottiem, Tilokskulchai, Vichitsukon and Kolatat (2004) who studied the effects of supine with flexion and side lying positions on the level of oxygen saturation, respiratory rates, heart rate, blood pressure and body temperature of preterm infants on mechanical ventilator as a guideline to calculate the effect size (Wiratchai, 1999) as follows:

$$d = (Y_E - Y_C) / S$$

$$S = \sqrt{\frac{(N_E - 1)(S_E)^2 + (N_C - 1)(S_C)^2}{N_E + N_C - 2}}$$

When

Y_E = The average mean for the experimental group (- 6.19)

Y_C = The average mean for the control group (- 3.90)

N_E = The size of the experimental group

N_C = The size of the control sample group

S_E = Standard Derivation of the experimental group

S_C = Standard Derivation of the control group

$$\text{Summary } S = \sqrt{\frac{(29)(4.06)^2 + (29)(3.61)^2}{30 + 30 - 2}} = 3.84$$

$$d = -6.19 - (-3.90) / 3.84 \\ = -0.59$$

The estimated size of the sample will obtain from the table of Cohen (1988) with effect size = - 0.59, $\alpha = 0.05$ and Power = 0.8 in estimating the sample size group by using t-test for independent mean. The effect size was obtained at between medium and large effect size to an approximate value of 19 subjects per group. Therefore, the sample in each group will be 23 infants to cover 20 % of attrition rate or incomplete data.

The control group: 23 infants in this group were obtained from retrospective chart review with in the past year. The inclusion criteria was the same as the experimental group.

The experimental group: 23 infants in this group were obtained from infant who are currently admitted in the NICU Phranakornsri Ayutthaya Hospital. The infants were selected according to the inclusion criteria.

Setting

This study took place in the Neonatal Intensive Care Unit (NICU) of Phranakornsri Ayutthaya Hospital which admits preterm infants with problems that require mechanical ventilators and intensive care monitors. These infants are cared in incubators with a pulse oximeter to monitor heart rate and oxygen saturation. Blankets inside the incubator are rolled in a 'nest' in order to help arrange positions and control body temperature. The temperature of room air must be not less than 27 ° C. Routine nursing care for preterm infants on mechanical ventilator in NICU at Phranakornsri Ayutthaya Hospital includes the following:

1. Upon the admission of a patient requiring the use of the mechanical ventilator, physicians set the ventilator and form a clear plan for treatment in the order treatment form.
2. Nurses monitor and observe the condition of the infants on the mechanical ventilator by using a pulse oximeter to monitor and follow up on the infants at the initial stage of mechanical ventilator use, observing and recording the condition every 5 minutes for a hour. If the infant is in stable condition, nurses will observe and record every 15 - 20 minutes for a period of 2 hours. For infants in stable condition who do not exhibit agitation or irregular symptoms such as heart rate < 100 beat per minute or > 160 beats per minute and in which breathing appears to be compatible with the mechanical ventilator, nurses will monitor every 1 -2 hours. However, infants who continue to exhibit unstable conditions such as desaturation and breathing that is incompatible with the mechanical ventilator will be monitored every 5 minutes.

3. While the infant is on the mechanical ventilator, routine nursing care includes evaluation and suction air way every 2 -3 hours. After suction air way, nurse arranges position suitable for the comfort of the infant. In case where the infant is in crisis, supine position will be arranged for easy observation. However, infants in stable condition will be placed in position suitable for the infant.

4. Infants on mechanical ventilator can be fed through an O – G tube as appropriate with careful observation during feeding.

When the infant's condition improves and stabilizes, physician will decide whether or not to initiate weaning off the mechanical ventilator. At the NICU of Phranakornsri Ayutthaya Hospital, the procedures of weaning off the mechanical ventilator are as follows:

1. The physician consider to wean off the mechanical ventilator and order in treatment form.

2. FiO₂ will be gradually weaned 5 % every 30 minutes. If no desaturation or HR > 160 beats per minute occurs, the oxygen will be continually weaned until the completion of the treatment plan.

3. When FiO₂ has been weaned to the completion of the treatment plan, the positive inspiratory pressure (PIP) or respiratory rate (RR) of the mechanical ventilator will begin to be weaned according to the treatment plan and O₂ Sat will be observed every 30 minutes. If no desaturation or heart rate > 160 bpm. occurs, and the infant breathes on his / her own without the use of abdominal muscles to aid breathing or there is no retraction (RR ≤ 60 beats per minute), respiratory rate stabilizes and the mode of the mechanical ventilator is set at CPAP (Continuous Positive Airway Pressure)

4. If the infant exhibits no irregular symptoms, no retraction is evident in breathing and the mechanical ventilator rate is ≤ 60 beat per minute, the physician will consider extubation of the endotracheal tube, using a Nasal CPAP in its place to monitor O₂ Saturation, heart rate and respiratory rate every 30 minutes.

Instruments

The instruments in this research consisted of the following:

1. Instruments used for conducting the research

1.1 Pulse oximeter of the Nellcor Puritan pulse N-550 Oximeter.

1.2 Equipment used for making a ‘nest’ for preterm neonates consisted of 60 x 80 cm. and 80 x 90 cm. blankets with the 80 x 90 cm blanket as a sheet and the 60 x 80 cm blanket rolled up lengthwise and placed on the blanket used as a sheet with the rolled-up blanket in a U-shape above the head of the infant (Figure 3.1; 3.2). The size of the U-shape should fit the size of the infant’s body and the ends of the ‘U’ should be above the head area of the infant (Figure 3.3).

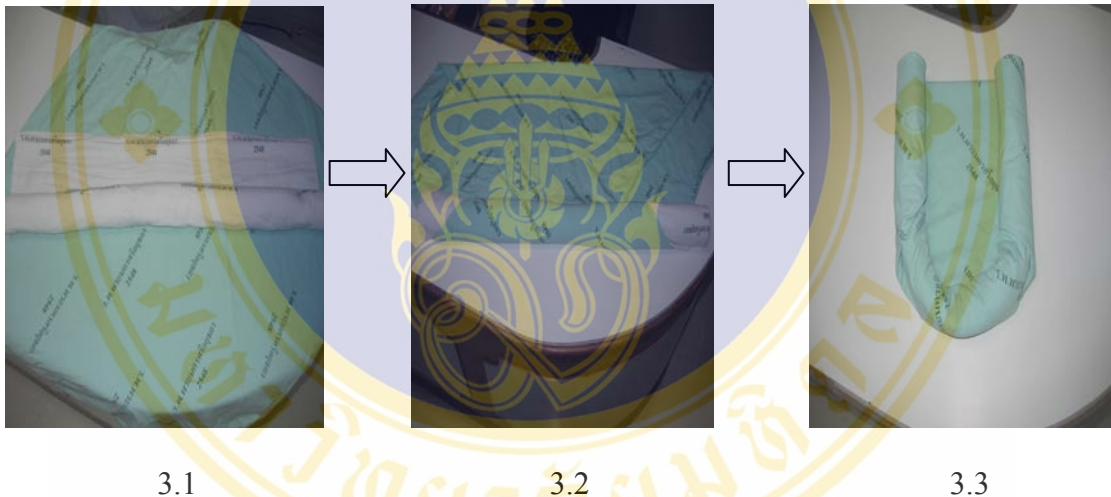


Figure 3: The step of making “Nest” in this study.

2. Instruments used for data collection

2.1 Personal data record form will be used to record demographic data and personal information: sex, gestational age, birth weight, time of birth, age of the infants at the time of the study, diagnosis, the mechanical ventilator setting as recorded prior to weaning, the date of initial weaning and the date of extubated endotracheal tube.

2.2 Data record form use the modified version of the Phranakornsri Ayutthaya Hospital NICU form record oxygen saturation, vital signs such as body temperature, heart rate and respiratory rates and respiratory characteristics including the setting of the mechanical ventilator and position of infants.

Validity and Reliability

The pulse oximeter was the Nellcor Puritan Bennett N-550 Pulse oximeter was inspected and calibrated by the Medical Engineering Division Company. The same pulse oximeter was used with the infants throughout this study.

Data collection

Data were collected according to the following process:

1. The research proposal was submitted to Ethical Committee of Phranakornsri Ayutthaya Hospital for ethical approval.
2. Permission for data collection was obtained from the Director of Phranakornsri Ayutthaya Hospital.
3. The researcher met the head nurse and staff nurses of Neonatal Intensive Care Unit in order to explain the details of the research and request co-operation to collect research data from the sample group.
4. The researcher chose a population for participation in the study according to established inclusion criteria and asked their parents to participate in the study. Informed consent was obtained from those who were willing to participate.
5. The data from the control group who received only routine care during weaning off the mechanical ventilator were collected from chart audit including oxygen saturation; heart rate; respiratory rate; time of beginning to wean off the mechanical ventilator and the time of extubated endotracheal tube.
6. The researcher began to collect data for the experimental group upon the confirmation of the physician that infants in the sample group were ready to be weaned off the mechanical ventilator. The researcher posed the infant in the side lying position as follows:
 - 6.1 the researcher randomly assigned the infant to left or right side lying position.
 - 6.2 The researcher used a pulse – oximeter to measure oxygen saturation and heart rate by application of a probe attached to either the hand or foot of the infants.
 - 6.3 The researcher began to arrange position for infant according to the following criteria:

- For infants being weaned in the morning, the infant's position were arranged after the following routine care: suction air way, diaper change (highly absorbent disposable diapers) and feeding at approximately 9:00 AM.

- For infants being weaned in the afternoon, the researcher arranged the infant's position after the following routine care: suction air way, hygiene care and diaper change (highly absorbent disposable diapers) and feeding at approximately 15.00 PM.

- Initial oxygen saturation, heart rate, respiration rate were recorded.

6.4 During the procedure of positioning, the endotracheal tube was securely stabilized to prevent accidental extubation and kink, arranging a suitable environment by covering the incubator to reduce light and the temperature of the incubator to approximately 36.8 – 37.2⁰ C were all adjusted.

6.5 The researcher recorded data of oxygen saturation, heart rate, respiratory rate and time to begin weaning off the mechanical ventilator.

6.6 After the position has been arranged and the infant has calm down for 15 minutes, record the time of weaning was begun with the oxygen saturation, heart rate and respiration rate as baseline data; and further record oxygen saturation, heart rate and respiratory rate every 15 minutes in 1 hour. When the infant has fallen asleep or is quiet, record the oxygen saturation, heart rate and respiratory rate every 30 minutes for observation and follow up by disturbing the infant as little as possible.

6.7 The researcher weaned setting of parameter of ventilatory in treatment form. The physician would order to repeat blood gas. During weaning, the researcher would record and observe sign and symptom of infants if the infant had poor clinical change from the weaning process they would stop weaning.

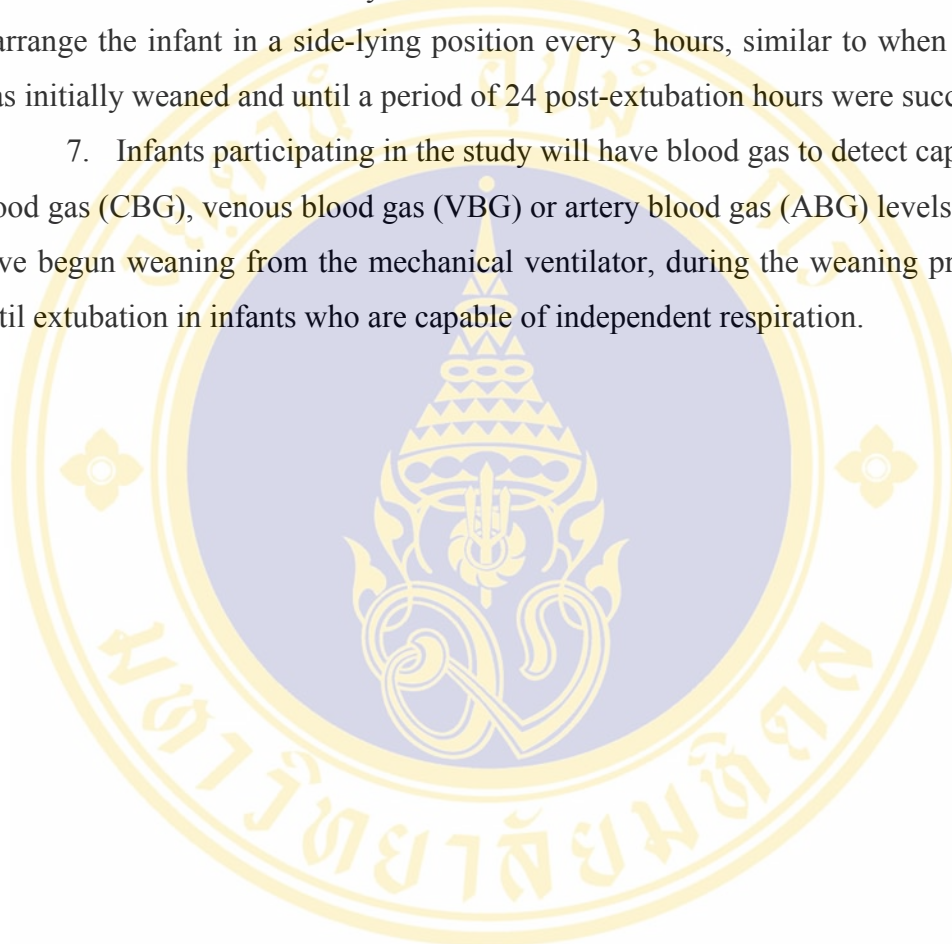
6.8 When the infant is improvable, the physician will consider extubation in which the infant will be supine position. Following extubation, the infant will have a nasal CPAP attached in order to prevent oxygen deficiency. Then the infant's position can be rearranged back to the previous side lying position for 3 hours.

6.9 Close monitoring is required and oxygen saturation, heart rate and respiratory rate should be recorded every 15 minutes until 1 hour, if irregular breathing occur i.e. gasping, hyperventilation (RR > 60 bpm), use abdominal muscles

for breathing or an oxygen saturation $< 92\%$, immediately resolve the problem and notify the physician; however, if the infant exhibits no irregularities, record the oxygen saturation, heart rate and respiratory rate every 30 minutes for the purpose of observation and follow up for a period of 24 hours.

6.10 Record the day and time of extubation in the data form and rearrange the infant in a side-lying position every 3 hours, similar to when the infant was initially weaned and until a period of 24 post-extubation hours were success.

7. Infants participating in the study will have blood gas to detect capillary blood gas (CBG), venous blood gas (VBG) or artery blood gas (ABG) levels after they have begun weaning from the mechanical ventilator, during the weaning process and until extubation in infants who are capable of independent respiration.



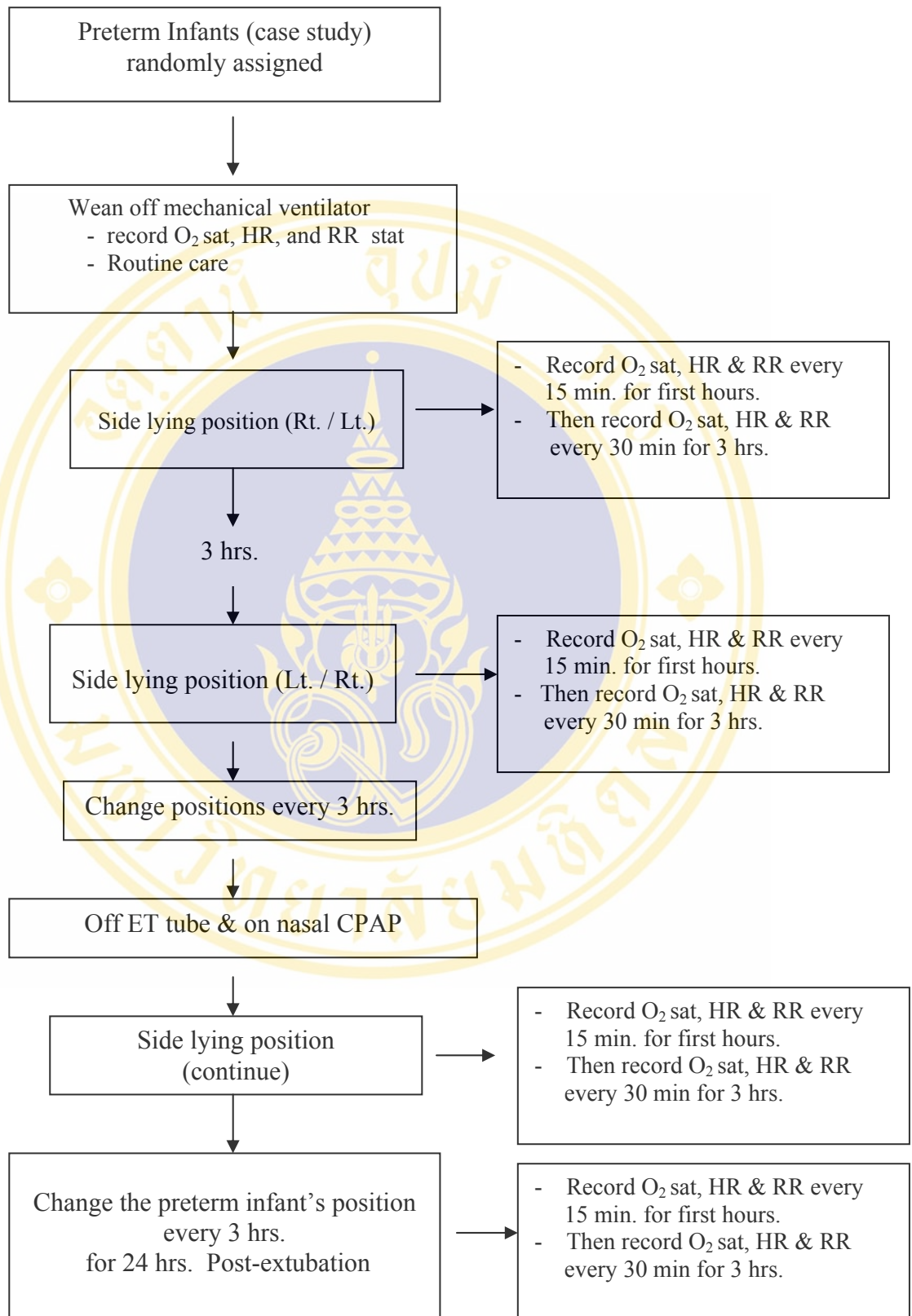


Figure 4: Diagram of data collection process in side lying position

Protection of Human Subjects

The steps of protection of human subjects were ascertained before the study as follows:

1. The researcher submitted all related documents: the proposal, participant information sheet and consent form to the Ethical Committee of Phranakornsri Ayutthaya Hospital for ethical approval.
2. After approving from the Ethical Committee of Phranakornsri Ayutthaya Hospital, the researcher selected subjects by explaining the objectives, methodology and period of time involved in the research. The researcher elicited the consent of the parents of the sample group for participation in the study voluntarily.
3. All information obtained from the participants will be kept confidentiality and anonymity. The data will be present as the group information.

Data Analysis

Data was analyzed by the application of a computer program which analyzed the details as follows:

1. Demographic data was analyzed with respect to distribution of frequency and percentage in each group.
2. Research data included the following:
 - 2.1 Values of oxygen saturation, heart rate, respiratory rate and the number of hours used in weaning from the mechanical ventilator were analyzed with regard to mean and standard deviation in each group.
 - 2.2 The differences in oxygen saturation, heart rate and respiratory rate while being weaned off the mechanical ventilator and the number of hours during weaning off the mechanical ventilator were tested by t- test and repeated measure of ANOVA.

CHAPTER IV

RESULTS

This study was a quasi-experimental design aimed to compare the effects of side lying and regular positions on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off the mechanical ventilator. The sample composed of 46 preterm infants on mechanical ventilator during weaning period, and admitted in the NICU at Phranakornsri Ayutthaya Hospital. The results in this study were presented in two parts as follows:

- Part I: The demographics of the subject
- Part II: Hypothesis testing

Part I: The demographics of the subject

The subjects were 46 preterm infants divided into regular position (n = 23) and side lying position (n = 23). In regular position there were 15 male infants (65.20 %) and 8 female infants (34.80 %) with gestational age mostly between 30-35 weeks (73.90%), and birth weight 1001-1500 grams (43.48 %). Most of them were diagnosed as respiratory distress syndrome; RDS (82.61 %). In side lying position there were 11 male infants (47.80 %) and 12 female infants (52.20 %) with gestational age mostly between 30-35 weeks (73.90 %), and birth weight in this study was 1001-1500 grams (39.13 %). Most of them were diagnosed as RDS (73.91 %). There was not significant different in demographics of subjects in both groups. However, there were more number of accidental extubation in infants with regular position than infants in side lying position significantly ($p < .05$).

Table 1: Preterm infants demographics (n = 46)

Characteristic	Regular position (n = 23)		Side lying position (n = 23)		χ^2	
	No	%	No	%		
Sex	Male	15	65.20	11	47.80	1.415 ^{ns}
	Female	8	34.80	12	52.20	
Gestational age (weeks)	25- 29	6	26.10	6	26.10	0.000 ^{ns}
	30 - 35	17	73.90	17	73.90	
Age of infants on the studied day	2 - 4 days	18	78.30	21	91.30	2.431 ^{ns}
	5 - 7 days	3	13.00	2	8.70	
	> 7 days	2	8.70	0	0.00	
Birth weight	< 1000 grams	1	4.35	0	0.00	2.111 ^{ns}
	1001 - 1500 grams	10	43.48	9	39.13	
	1501 - 2000 grams	9	39.13	8	34.78	
	> 2000 grams	3	13.04	6	26.09	
Delivery	Normal	11	47.82	13	56.52	0.553 ^{ns}
	Abnormal					
	- Caesarean section	10	43.48	9	39.13	
	- Breech assisting	2	8.70	1	4.35	

ns = non significant

Table 1: Preterm infants demographics (n = 46) (continued)

Characteristic	Regular position (n = 23)		Side lying position (n = 23)		χ^2	
	No	%	No	%		
APGAR score at 1 minute	> 3 - 5	3	13.04	7	30.43	3.650 ^{ns}
	> 5-7	7	30.43	9	39.14	
	>7	13	56.53	7	30.43	
APGAR score at 5 minute	> 3 - 5	0	0	3	13.04	3.366 ^{ns}
	> 5-7	7	30.43	5	21.74	
	>7	16	69.57	15	65.22	
Diagnosis	Mild RDS	4	17.39	1	4.35	3.256 ^{ns}
	Moderate RDS	9	39.13	8	34.78	
	Severe RDS	6	26.09	8	34.78	
	RDS with pneumonia	4	17.39	5	21.74	
	MAS	0	0	1	4.35	
Number of accidental extubation during wean (time)	None	12	52.17	20	86.95	9.333*
	1	10	43.48	2	8.70	
	2	0	0	1	4.35	
	4	1	4.35	0	0	

RDS = Respiratory Distress Syndrome

MAS = Meconium Aspirate Syndrome

*p < .05; ns = non significant

Part II: Hypothesis testing

Hypothesis 1: Mean oxygen saturation in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

There was not significant different in mean oxygen saturation between side lying position and regular position ($p > .05$). During weaning process, the mean oxygen saturation of preterm infants in this study did not different when they were placed in the regular position or side lying position. (Table 2)

Table 2: The result of t- test analysis with mean oxygen saturation during weaning process (n = 46)

	Regular position (n = 23)		side lying position (n = 23)		t – test
	\bar{X}	SD.	\bar{X}	SD.	
Oxygen saturation before wean (%)	98.26	1.738	97.74	1.711	1.026 ^{ns}
Oxygen saturation at the beginning of weaning process (%)	98.17	1.497	97.70	1.636	1.034 ^{ns}
Oxygen saturation during wean (%)	97.39	0.898	97.19	1.027	0.697 ^{ns}
Oxygen saturation post extubation (%)	96.21	2.261	97.20	1.009	-1.919 ^{ns}

$p < .05$; ns = non significant

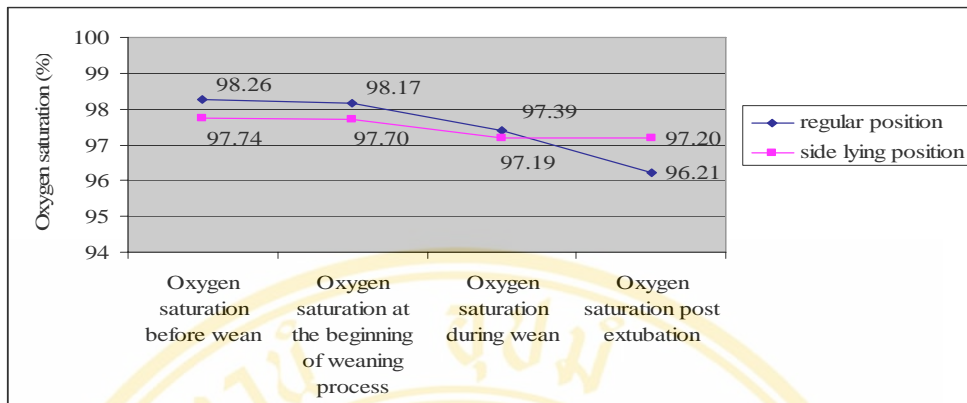


Figure 5: Compared mean oxygen saturation of preterm infants during weaning process between regular position and side lying position.

The result from repeated measure ANOVA and Post Hoc analysis showed that the mean of oxygen saturation in each period of weaning process in infants with regular position was different from the post extubation ($p < .05$).

Table 3: Repeated measure of analysis of variance of mean oxygen saturation during weaning process of each group (regular position and side lying position).

Variable	df	SS	MS	F
Regular position				
Oxygen saturation during weaning process				
Between Groups	3	62.555	20.852	7.459*
Within Groups	88	245.999	2.795	
Side lying position				
Oxygen saturation during weaning process				
Between Groups	3	6.332	2.111	1.100 ^{ns}
Within Groups	88	168.877	1.919	

* $p < .05$; ns = non significant

Table 4: Post Hoc analysis of mean oxygen saturation in preterm infants with regular position during weaning process

Variable		Before wean	At the beginning of weaning process	During wean	Post extubation
	\bar{X}	98.26	98.17	97.39	96.21
Before wean	98.26	-	-	-	2.05*
At the beginning of weaning process	98.17	-	-	-	1.97*
During wean	97.39	-	-	-	1.18*
Post extubation	96.21	-2.05*	-1.97*	-1.18*	

* p < .05

Hypothesis 2: Mean heart rates in infants with side lying position will be different from regular positions during weaning off mechanical ventilator.

There was not significant different in mean heart rate between side lying position and regular position (p > .05). The preterm infants in the weaning process was not different the mean heart rate both regular and side lying position. (Table 5)

Table 5: The result of t- test analysis with mean of heart rate during weaning process (n = 46)

	regular position (n = 23)		side lying position (n = 23)		t – test
	\bar{X}	SD	\bar{X}	SD.	
Heart rate before wean (bpm.).	150.83	14.031	145.09	11.273	1.529 ^{ns}
Heart rate at the beginning of weaning process (bpm.)	144.78	17.763	143.00	13.484	0.383 ^{ns}
Heart rate during wean (bpm.)	142.33	9.852	143.74	12.033	-0.434 ^{ns}
Heart rate post extubation (bpm.)	140.66	8.868	143.19	11.863	-0.821 ^{ns}

p < .05; ns = non significant

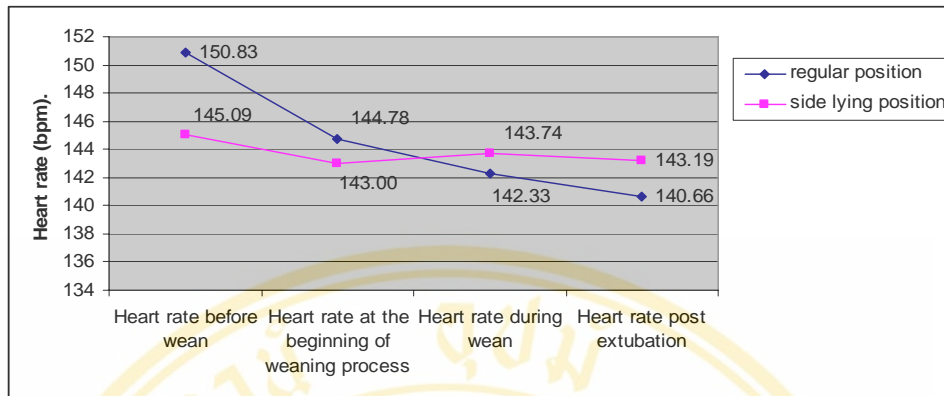


Figure 6: Compared mean heart rate of preterm infants during weaning process between regular position and side lying position

The result from repeated measure ANOVA and Post Hoc analysis showed that the mean of heart rate before weaning of infants with regular position was different from during weaning and post extubation in weaning process ($p < .05$).

Table 6: Repeated measure of analysis of variance in the mean heart rate during weaning process of each group (regular position and side lying position)

Variable	df	SS	MS	F
Regular position				
Heart rate during weaning process				
Between Groups	3	1367.768	455.923	2.650*
Within Groups	88	15138.804	172.032	
Side lying position				
Heart rate during weaning process				
Between Groups	3	61.158	20.386	0.137 ^{ns}
Within Groups	88	13077.082	148.603	

* $p < .05$; ns = non significant

Table 7: Post Hoc analysis of mean heart rate in the preterm infants with regular position during weaning process

Variable	\bar{X}	At the beginning			
		Before wean	of weaning process	During wean	Post extubation
		150.83	144.78	142.33	140.66
Before wean	150.83	-	-	8.49*	10.17*
At the beginning of weaning process	144.78	-	-	-	-
During wean	142.33	- 8.49*	-	-	-
Post extubation	140.66	- 10.17*	-	-	-

*p < .05

Hypothesis 3: Mean respiratory rates in infants with side lying position will be different from regular positions during weaning off mechanical ventilator.

There was a significant different mean respiratory rate between side lying position and regular position (p < .05). In this study found that the mean respiratory rate in side lying was higher than regular position during weaning process. (Table 8)

Table 8: The result of t- test analysis with mean of respiratory rate during weaning process (n = 46)

	regular position (n = 23)		side lying position (n = 23)		t – test
	\bar{X}	SD.	\bar{X}	SD.	
Respiratory rate before wean (bpm).	44.43	4.176	43.13	4.506	1.018 ^{ns}
Respiratory rate at the beginning of weaning process (bpm)	44.78	4.067	47.00	6.895	-1.328 ^{ns}
Respiratory rate during wean (bpm).	45.82	2.148	51.16	4.363	-5.268*
Respiratory rate post extubation (bpm).	47.10	3.146	50.54	4.335	-3.087*

*p < .05; ns = non significant

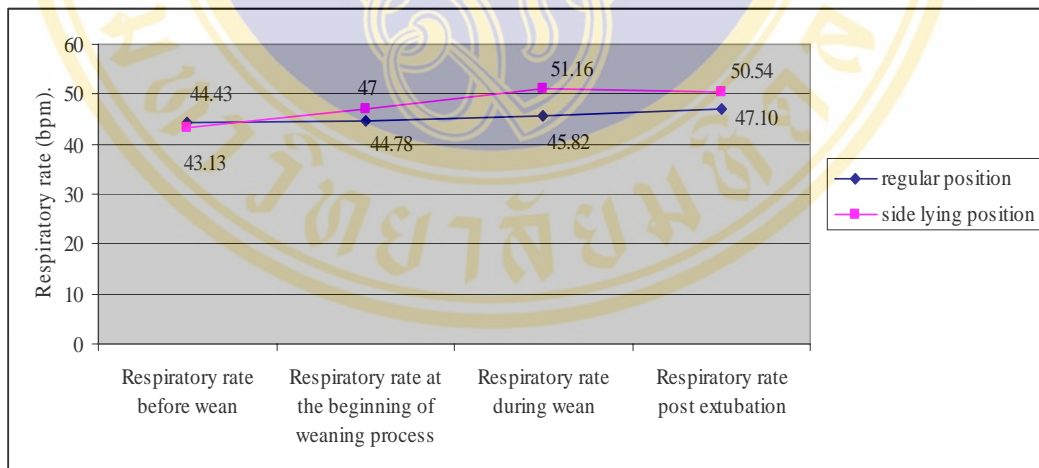


Figure 7: Compared mean respiratory rate of preterm infants during weaning process between regular position and side lying position

The result from repeated measure of ANOVA and Post Hoc analysis showed that the mean of respiratory rate of preterm infants with regular position before wean and at the beginning of weaning process was different from the post extubation (p < .05) (Table 10) and the mean of respiratory rate of preterm infants with side lying

position in each period of weaning process was different from the next period ($p < .05$). (Table 11)

Table 9: Repeated measure of analysis of variance of the mean respiratory rate during weaning process of each group (regular position and side lying position)

Variable	df	SS	MS	F
Regular position				
Respiratory rate during weaning process				
Between Groups	3	98.764	32.921	2.716*
Within Groups	88	1066.828	12.123	
Side lying position				
Respiratory rate during weaning process				
Between Groups	3	946.327	315.442	11.940*
Within Groups	88	2324.822	26.418	

* $p < .05$

Table 10: Post Hoc analysis of mean respiratory rate in the preterm infants with regular position during weaning process

Variable	Before wean	At the beginning of weaning process	During wean	Post extubation	
	\bar{X}	44.43	44.78	45.82	47.10
Before wean	44.43	-	-	-	- 2.66*
At the beginning of weaning process	44.78	-	-	-	- 2.31*
During wean	45.82	-	-	-	-
Post extubation	47.10	- 2.66*	-2.31*	-	-

* $p < .05$

Table 11: Post Hoc analysis of mean respiratory rate in the preterm infants with side lying position during weaning process

Variable		Before wean	At the beginning of weaning process	During wean	Post extubation
	\bar{X}	43.13	47.00	51.16	50.54
Before wean	43.13	-	-3.78*	-8.03*	-7.41*
At the beginning of weaning process	47.00	3.78*	-	-4.16*	-3.54*
During wean	51.16	8.03*	4.16*	-	-
Post extubation	50.54	7.41*	3.54*	-	-

*p < .05

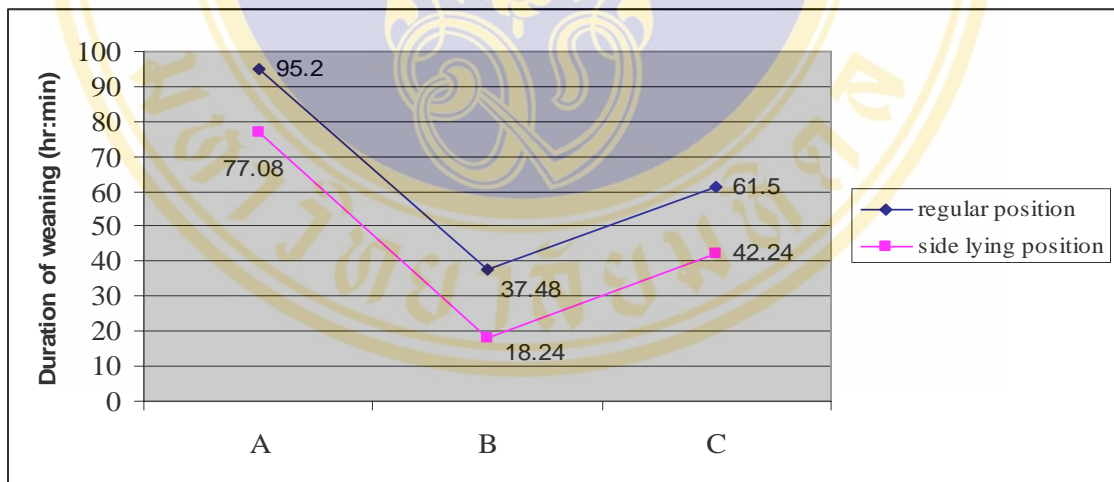
Hypothesis 4: The duration of weaning in infants with side lying position will be different from regular position during weaning off mechanical ventilator.

There was a significant different the duration of weaning process between side lying position and regular position ($p < .05$) and found that the side lying position was decreased ventilatory parameter faster than regular position ($p < .05$). (Table 12)

Table 12: The result of t- test analysis with mean of the duration of weaning process
(n = 46)

Variable	Regular position (n = 23)		Side lying position (n = 23)		t-test
	\bar{X}	S.D.	\bar{X}	S.D.	
Duration of using mechanical ventilator (hr:min)	95.20	59.52	77.08	32.41	1.279 ^{ns}
Duration of decreasing ventilatory parameter (hr:min)	37.40	18.00	18.24	9.59	4.518*
Duration of successful weaning (hr:min)	61.50	18.01	42.24	9.59	4.522*

*p < .05; ns = non significant



A: Duration of using mechanical ventilator (from the first day of using until the initial time of weaning)

B: Duration of decreasing ventilatory parameter (from the initial time of weaning to the time of extubation)

C: Duration of successful weaning (from the time of extubation until 24 hours post extubation)

Figure 8: Compared mean of duration of time during weaning process between regular position and side lying position

The result from repeated measure of ANOVA and Post Hoc analysis showed that the mean duration of weaning in each period of weaning process was different from the next period ($p < .05$). (Table 14; 15)

Table13: Repeated measure of analysis of variance of the mean duration of weaning process of each group (regular position and side lying position)

Variable	df	SS	MS	F
Regular position				
Time during weaning process				
Between Groups	2	138283489.855	69141744.928	13.609*
Within Groups	66	335321676.087	5080631.456	
Side lying position				
Time during weaning process				
Between Groups	2	144418357.246	72209178.623	47.440*
Within Groups	66	100459869.565	1522119.236	

* $p < .05$

Table 14: Post Hoc analysis of the mean duration of weaning process in the preterm infants with regular position

Variable	\bar{X}	Using mechanical ventilator	Decrease ventilatory parameter	Duration of successful weaning
		95.20	37.48	61.50
Using mechanical ventilator	95.20	-	3452.17*	2009.57*
Decrease ventilatory parameter	37.48	-3452.17*	-	-1442.61*
Duration of successful weaning	61.50	-2009.57*	1442.61*	-

* $p < .05$

Table 15: Post Hoc analysis of the mean duration of weaning process in the preterm infants with side lying position

Variable	—	Using mechanical ventilator	Decrease ventilatory parameter	Duration of successful weaning
	X	77.08	18.24	42.24
Using mechanical ventilator	77.08	-	3524.35*	2082.83*
Decrease ventilatory parameter	18.24	-3524.35*	-	-1441.52*
Duration of successful weaning	42.24	-2082.83*	1441.52*	-

*p < .05

CHAPTER V

DISCUSSION

This study was the quasi – experimental design to compare the effects of side lying position and regular position on oxygen saturation, heart rate, respiratory rate and duration of weaning in preterm infants during weaning off the mechanical ventilator. The result of this study was discussed as follows:

Hypothesis 1: Mean oxygen saturation in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

The result in this study found that mean oxygen saturation in infants with side lying position was not significant different from infants with regular position during weaning off mechanical ventilator ($p > .05$) which did not support the proposed hypothesis.

From the review of literature, this might be explained from the fact that infant with mechanical ventilator will be allowed to wean off when clinical signs, blood gas and oxygen saturation were in the accepted level (blood gas: $\text{pH} > 7.25$; $\text{pCO}_2 < 40$ mmHg; & $\text{HCO}_3 22 - 26 \mu\text{mol/l}$. and oxygen saturation $> 95 \%$). Therefore, in this study these parameters were not significant different between infant in regular and side lying position. However the infants with side lying position had stabilized oxygen saturation than regular position during weaning process (side lying position 97.74, 97.70, 97.19 and 97.20 % vs regular position 98.26, 98.17, 97.39 and 96.21 %). This result might due to the side lying position promotes gas exchange and decreases secretion obstruction as well as promote secretion drainage resulted in easier to suction. In addition, the proper positions promote subsystem function of infants to calm down the infants and save energy expenditure. Therefore, the infant with side lying position maintained stabilization of oxygen saturation. This finding was congruent with the finding of Antunes et al. (2003) who studied the effect of prone position on cardiorespiratory and weaning outcome of the preterm infants during

weaning off mechanical ventilator. The subject was 42 preterm infants with average gestation age 29 weeks and birth weight less than 2000 grams who were on mechanical ventilator during the first week of life. They found that transcutaneous oxygen saturation, heart rate and respiratory rate were not different significantly between prone and supine position but oxygen desaturation episode was more frequent in supine position ($p = .009$) and ventilatory parameters decrease faster in the prone group. In the study of Jirapaet et al. (1994) who studied the effect of posture (prone, supine, right and left side lying position) on oxygen saturation and respiratory status (respiratory rate and Silverman-Aderson retraction score) within 48 hours post extubation of 15 preterm infants with mean birth weight 1251 grams (range 610-1800 grams), mean postnatal age 18.87 days (range 2-39 days) and mean post extubation period 23.5 hours. The result revealed that there was not significant different of mean oxygen saturation and Silverman-Aderson retraction score between each position (prone and supine position) but they found that respiratory rate in side lying was higher than prone and supine position significantly ($p = .001$). The result of this study was different from the systematic review of infant position in neonates receiving mechanical ventilation conducted by Balagure et al. (2003), they reviewed ten trials involving 164 infants and found that the prone position slightly improved oxygenation in neonate undergoing the mechanical ventilator. Regarding the oxygenation of infants on mechanical ventilator who were posed in different position, Yottiem and associates (2004) found that infant with side lying position and supine with flexion position increase oxygen saturation than infant with regular position significantly ($p = .000$).

Hypothesis 2: Mean heart rate in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

The result in this study found that mean heart rate in infants with side lying position was not significant different from infant with regular position during weaning off mechanical ventilator ($p > .05$), which did not support the proposed hypothesis.

From the review of literature, this might be explained with the same reason as oxygen saturation that infant with mechanical ventilator will be allowed to wean off when the heart rate was in the accepted normal range (120 – 160 bpm). Therefore, the result of this study found that mean heart rate was not significant different between

side lying position and regular positions ($p > .05$). However the infants with side lying position had stabilized heart rate than regular position during weaning process (side lying position 145.09, 143, 143.74 and 143.19 bpm. vs regular position 150.83, 144.78, 142.33 and 140.66 bpm.). This result was congruent with the findings of Antunes et al. (2003) who studied the effect of prone position on cardiorespiratory response and weaning outcome of the preterm infants during weaning off mechanical ventilator and found that there was not significant different of heart rate in prone and supine position ($p > .05$). As well as the result of Yottiem et al. (2004), they studied preterm infants with assisted mechanical ventilator on oxygenation, heart rate, respiration rate, blood pressure and body temperature in different position and found that the heart rate was not significant different between side lying position, supine with flexion and regular position ($p > .05$).

Hypothesis 3: Mean respiratory rate in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

This study found that the mean respiratory rate in infants with side lying position was significant different from regular position during weaning off mechanical ventilator ($p < .05$) which supported the proposed hypothesis.

The findings found that the mean respiratory rate in side lying position during weaning off and post extubation was higher than regular position. This might be due to the limitation of lung movement in the side lying position, so they will compensate by increasing respiratory rate and more expansion of upper lung. This result was congruent with the findings of Jirapaet et al. (1994), who studied the effect of posture on oxygen saturation and respiratory status within 48 hours post extubation with preterm infants. They found that respiratory rate in side lying position was higher than prone position and supine position significantly ($p = .001$). However, this study was different from Antunes et al. (2003), they studied the effect of prone position and supine position during weaning off mechanical ventilator and found that there was not significant different in respiratory rate between prone and supine position ($p > .05$). In addition, it was not congruent with the findings of Yottiem et al. (2004), who studied the position of preterm infants with assisted mechanical ventilator and found that there

was not significant different in respiratory rate between side lying position, supine with flexion and regular position ($p > .05$).

Hypothesis 4: The duration of weaning in preterm infants with side lying position will be different from regular position during weaning off mechanical ventilator.

The result of this study found that the duration of weaning in infants with side lying position was significant different from regular position during weaning off mechanical ventilator ($p < .05$) which supported the proposed hypothesis.

From the review of literature, the side lying position is a proper position because it is similar to the position in intrauterine which helps infant to calm down, to be able to adapt with the environmental change efficiently, and support subsystems of infant. In addition, the findings found that the infant with side lying position can significant reduced many ventilatory parameters faster than regular position ($p < .05$). This finding was congruent with the findings of Antunes et al. (2003), who studied the effect of prone position and supine position during weaning off mechanical ventilator on cardiorespiratory and weaning outcome in preterm infants and found that the prone position can reduced ventilatory parameter and reintubation than supine position (4 % vs 33 %). Moreover, in this study there was more accidental extubation in regular position than side lying position during weaning off mechanical ventilator significantly (47.83 % vs 13.05 %).

CHAPTER VI

CONCLUSION

Summary of the Study

This research was a quasi-experimental design aimed to compare the effects of the side lying position versus the regular position on oxygen saturation, heart rate, respiratory rate and duration of weaning during the process of weaning off mechanical ventilator. The sample composed of 46 preterm infants on mechanical ventilator during weaning period, who had gestational age less than 37 weeks and admitted in the Neonatal Intensive Care Unit (NICU) at Phranakornsri Ayutthaya Hospital.

Forty-six preterm infants, who received the mechanical ventilator at least 48 hours from birth or within the first week after delivery, were selected according to inclusion criteria. The results of this study are as follows:

1. Mean oxygen saturation in preterm infants with side lying position was not significant different from preterm infants with regular position during weaning off mechanical ventilator ($p > .05$).
2. Mean heart rate in preterm infants with side lying position was not significant different from preterm infants with regular position during weaning off mechanical ventilator ($p > .05$).
3. Mean respiratory rate in preterm infants with side lying position was significant different from preterm infants with regular position during weaning off mechanical ventilator ($p < .05$).
4. The duration of weaning in preterm infants with side lying position was significant different from preterm infants with regular position during weaning off mechanical ventilator ($p < .05$).

Implications and Recommendations

Implications to nursing practice

The results of this study support the notion that preterm infants in side lying position had stability of oxygen saturation, heart rate and shorter period of weaning off mechanical ventilator. Therefore, nurses in NICU should put infants in side lying position during weaning off mechanical ventilator.

In addition, it is noticeable that during the experimental period the preterm infants was observed closely and received attention from the researcher which resulted in good outcome in ventilatory parameters and duration of weaning. Therefore, it is recommended to develop clinical nursing practice guideline for taking care of infants from this evidence.

Recommendation for further study

This study should be replicated with a randomized controlled trial design in order to generate more rigorous evidence to support the benefit of side lying position in preterm infants during weaning off mechanical ventilator.

Limitations of the Study

The control group in this study was obtained from retrospective chart review which is in the different period from the experimental group. Therefore, there might be some confounding factors such as number of patients and workload of staff that might affect quality of nursing care in each period.

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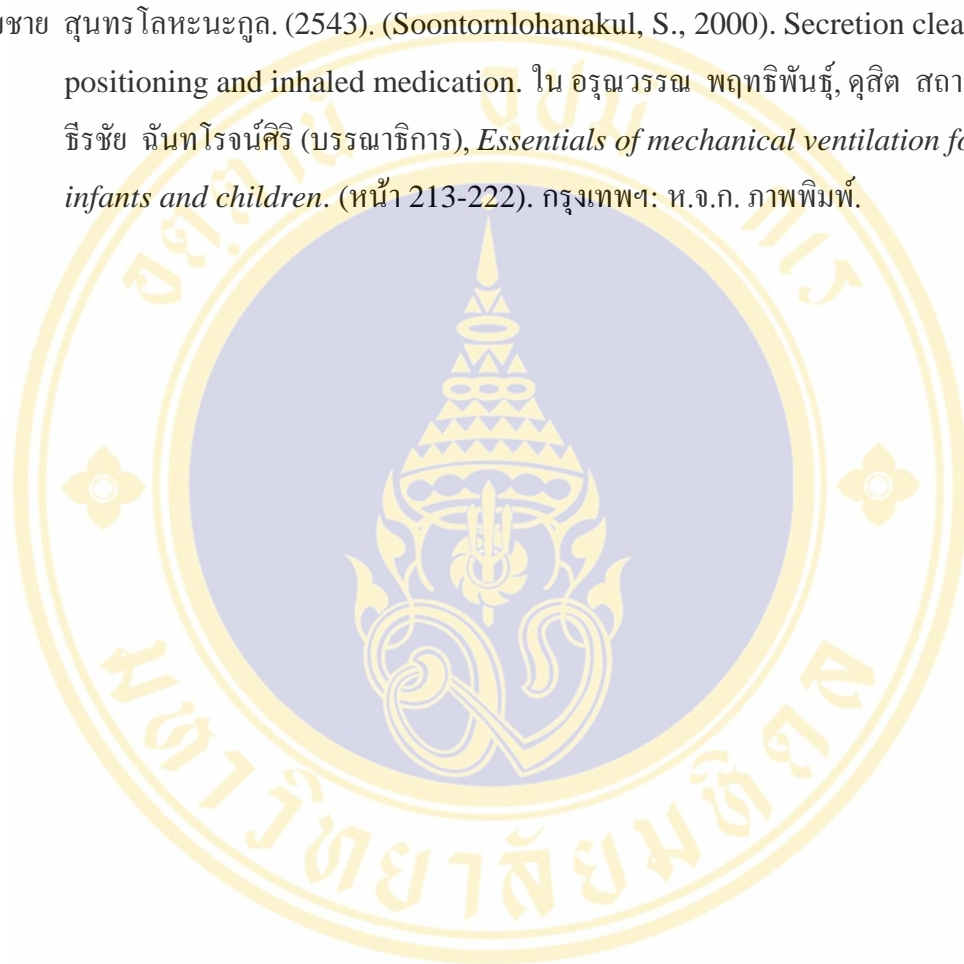
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เอกสารรับรองคณะกรรมการจริยธรรมการวิจัยในคน
โรงพยาบาลพระนครศรีอยุธยา

ชื่อโครงการ	ผลของการจัดทำนอนต่อค่าความอิ่มตัวของออกซิเจน สัญญาณชีพและระยะเวลาในการหย่าเครื่องช่วยหายใจของทารก เกิดก่อนกำหนดขณะหย่าเครื่องช่วยหายใจ “EFFECT OF POSTURE ON OXEGENATION, VITAL SIGNS AND TIME OF WEANING DURING WEAN OF MECHANICAL VENTILATOR IN PRETERM INFANTS.”
ชื่อหัวหน้าโครงการ	นางศรีสุรีย์ สุนพยานนท์
สังกัดหน่วยงาน	โรงพยาบาลพระนครศรีอยุธยา กองโรงพยาบาลภูมิภาค
เอกสารที่รับรอง	- โครงการวิจัย - หนังสือยินยอมและสมัครใจเข้าร่วมโครงการ

ได้ผ่านการพิจารณารับรองโดยคณะกรรมการจริยธรรมวิจัยในคน เมื่อวันที่ 14 มีนาคม 2549

(นายวิระพล ชีระพันธ์เจริญ)

ผู้อำนวยการโรงพยาบาลพระนครศรีอยุธยา



บันทึกข้อความ

ส่วนราชการ โรงพยาบาลพระนครศรีอยุธยา

ที่ อย 0027.1/ 05012

วันที่ 11 เมษายน 2549

เรื่อง แจ้งผลการพิจารณาโครงการวิจัย

เรียน นางศรีสุรีย์ สุนพยานนท์

ตามที่ท่านได้ส่งโครงการวิจัยเรื่อง ผลของการจัดท่านอนต่อค่าความอิ่มตัวของออกซิเจน
ตัวฐานชีพและระยะเวลาในการหย่าเครื่องช่วยหายใจของทารก เกิดก่อนกำหนดขณะหย่าเครื่องช่วย
หายใจ "EFFECT OF POSTURE ON OXEGENATION, VITAL SIGNS AND TIME OF
WEANING DURING WEAN OF MECHANICAL VENTILATOR IN PRETERM INFANTS." นั้น

จึงเรียนมาเพื่อทราบ และให้ดำเนินการวิจัยได้

(นายวิระพล ชีระพันธ์เจริญ)

ผู้อำนวยการ โรงพยาบาลพระนครศรีอยุธยา

APPENDIX B

Consent to Participate in Research Study

เอกสารชี้แจงข้อมูล / คำแนะนำแก่ผู้เข้าร่วมวิจัย

- หัวข้อเรื่องที่จะทำวิจัย: ผลของการจัดทำนอนต่อค่าความอึดตัวของออกซิเจน สัญญาณชีพ และระยะเวลาในการหย่าเครื่องช่วยหายใจของทารกเกิดก่อนกำหนดที่หย่าเครื่องช่วยหายใจ
- วัตถุประสงค์และวิธีการวิจัย
การวิจัยครั้งนี้มีวัตถุประสงค์ เพื่อศึกษาเปรียบเทียบผลของการจัดทำนอนตะแคงข้าง และทำนอนปกติในทารกเกิดก่อนกำหนดที่กำลังหย่าเครื่องช่วยหายใจต่อค่าความอึดตัวของออกซิเจน อัตราการเต้นของหัวใจ อัตราการหายใจ และระยะเวลาในการหย่าเครื่องช่วยหายใจ โดยการวิจัยครั้งนี้เป็นการวิจัยเชิงกึ่งทดลองแบบ 2 กลุ่ม คือกลุ่มที่ได้รับการจัดทำนอนตะแคงข้าง และกลุ่มที่ได้รับการจัดทำนอนปกติของหน่วยงาน
- เหตุผลที่เชิญชวนให้พ่อ แม่ และผู้แทนโดยชอบธรรมยินยอมให้ทารกทำการเข้าโครงการวิจัย
เนื่องจากทารกของท่านเป็นทารกคลอดก่อนกำหนด ที่ใช้เครื่องช่วยหายใจ และกำลังหย่าเครื่องช่วยหายใจ ซึ่งเข้าได้กับเกณฑ์ในการคัดเลือกกลุ่มตัวอย่าง ซึ่งในการวิจัยครั้งนี้ต้องการข้อมูลจากทารกเกิดก่อนกำหนด ที่ใช้เครื่องช่วยหายใจ และกำลังหย่าเครื่องช่วยหายใจ เพื่อนำข้อมูลจากการวิจัยครั้งนี้มาเป็นข้อมูลสนับสนุนการดูแลทารกเกิดก่อนกำหนดที่กำลังหย่าเครื่องช่วยหายใจ และสนับสนุนการพยาบาลทารกเกิดก่อนกำหนดที่กำลังหย่าเครื่องช่วยหายใจ ได้มีประสิทธิภาพมากขึ้น
- ระยะเวลาที่ต้องทำการทดสอบผู้ยินยอมตนให้ทำการวิจัย
เมื่อท่านตัดสินใจให้ทารกเข้าร่วมการวิจัย ผู้วิจัยจะดำเนินการดังนี้ เมื่อแพทย์มีแผนการรักษาให้ทารกหย่าเครื่องช่วยหายใจ ทารกของท่านจะได้รับการจัดทำนอนจากผู้วิจัย โดยการจัดทำนอนตะแคงสลับข้างซ้าย และข้างขวา ผู้วิจัยจะจัดสลับข้างให้ทุก 3 ชั่วโมงตามการได้รับนมของทารกและเพื่อลดการรบกวนทารก ซึ่งทารกจะได้รับการจัดทำนอนตามแนวทางต่อไปนี้
การจัดทำนอนตะแคง วางม้วนผ้าที่ทำเป็นอาณาเขตทารก และจัดให้ทารกนอนกึ่งกลางของอาณาเขต โดยจะจัดทำนอนให้ทารกนอนหันหน้าและลำตัวไปทางด้านข้าง แขนทั้งสองข้างงอชิดเข้าหาแนวกึ่งกลางลำตัว และจัดให้มีมืออยู่ใกล้บริเวณปาก ข้อเท้า และข้อสะโพกอยู่ในท่างอสอดม้วนผ้าไว้ระหว่างแขน และขาทั้งสองข้าง และม้วนผ้ารองด้านหลังทารกป้องกันการพลิกหงายของทารกและจัดให้เท้าของทารกยันกับม้วนผ้าที่เป็นอาณาเขต ยกเว้นที่นอนให้สูง 15-30 องศา ในการจัดทำนอนตะแคงจะสลับให้ ทุก 3 ชั่วโมง จนเสร็จสิ้นการวิจัย

จากนั้นผู้วิจัยจะทำการเก็บข้อมูลในขณะที่ทารกได้รับการจัดท่านอน โดยการบันทึกผลของระดับความอึดตัวของออกซิเจนในเลือดที่ผิวหนัง อัตราการเต้นของหัวใจ และอัตราการหายใจทุก 15 นาทีจนครบ 1 ชั่วโมง เมื่อค่าเหล่านี้คงที่ ทารกไม่มีอาการเปลี่ยนแปลงจะบันทึกผลทุก 30 นาที จนครบ เวลา 3 ชั่วโมง ผู้วิจัยจะสลับเปลี่ยนข้างให้ทารกทุก 3 ชั่วโมง และเมื่อทารกได้รับการถอดท่อช่วยหายใจจะได้รับการจัดท่านอนต่อไปจนครบ 24 ชั่วโมง ซึ่งหลังจากที่เสร็จสิ้นการวิจัยทารกจะยังคงได้รับการดูแลจากหน่วยงานเช่นเดียวกับในขณะที่อยู่ในการวิจัย

5. ประโยชน์ที่คาดว่าจะเกิดขึ้นทั้งต่อผู้ยินยอมตนให้ทำการวิจัยและต่อผู้อื่น

สำหรับการวิจัยครั้งนี้ เป็นการจัดท่านอนที่เหมาะสมสำหรับทารกที่กำลังหย่าเครื่องช่วยหายใจ เพื่อส่งเสริมให้การแลกเปลี่ยนก๊าซในปอดมีประสิทธิภาพ ช่วยให้ระดับของออกซิเจนในเลือดสูงขึ้น อัตราการเต้นของหัวใจ อัตราการหายใจอยู่ในเกณฑ์ปกติ และส่งเสริมให้การหย่าเครื่องช่วยหายใจได้เร็วและมีประสิทธิภาพ รวมทั้งยังช่วยส่งเสริมพัฒนาการด้านต่างๆ ให้กับทารกเกิดก่อนกำหนด เช่น พัฒนาการด้านกล้ามเนื้อและข้อ พัฒนาการด้านระบบประสาท และสมองเป็นต้นและยังเป็นข้อมูลพื้นฐานในการเลือกจัดท่านอนที่เหมาะสมและมีประสิทธิภาพให้กับทารกที่ใส่ท่อช่วยหายใจและกำลังหย่าเครื่องช่วยหายใจในหออภิบาลทารกแรกเกิดต่อไป

6. ความเสี่ยงหรือความไม่สบายที่คาดว่าจะเกิดขึ้นกับผู้ยินยอมตนให้ทำการวิจัย ในการเข้าร่วมการศึกษาวิจัย

การจัดท่านอนทารกเกิดก่อนกำหนดในการศึกษาที่ผ่านมา พบว่าไม่มีอันตรายที่เกิดจากการจัดท่านอน และ ในขณะที่ดำเนินการวิจัย ผู้วิจัยจะใช้ความระมัดระวังในการประคับประคองท่อหลอดลมคอของทารกในขณะที่จัดท่านอน ซึ่งได้ปฏิบัติตามหลักการที่ถูกต้อง จึงไม่มีอันตรายที่จะเกิดกับตำแหน่งท่อหลอดลมคอ แต่อาจจะเกิดการเปลี่ยนแปลงของระดับของออกซิเจนในเลือด อัตราการเต้นของหัวใจ และอัตราการหายใจ ซึ่งไม่เป็นอันตรายต่อทารก

แต่ถ้าในกรณีที่มีการเปลี่ยนแปลงมากผู้วิจัยจะหยุดทำการวิจัยทันที และรายงานแพทย์ร่วมกับค้นหา และแก้ไขจนทารกดีขึ้นพร้อมทั้งให้การดูแลอย่างใกล้ชิด อย่างไรก็ตามถ้าพ่อแม่ผู้ดูแลทารกรู้สึกกังวลใจ และไม่พร้อมที่จะให้ทารกเข้าร่วมการวิจัยสามารถที่จะขอพักการวิจัยได้ทันที

7. ขอบเขตการดูแลรักษาความลับของข้อมูลต่างๆ ของผู้ยินยอมตนให้ทำการวิจัย

ข้อมูลทุกอย่างของทารก ผู้วิจัยจะเก็บเป็นความลับ การรายงานผลการวิจัยจะนำเสนอในภาพรวมเท่านั้น ไม่เปิดเผยชื่อ นามสกุลของทารกของท่านให้ผู้อื่นรับทราบ

8. สิทธิผู้ยินยอมคนให้ทำการวิจัยจะถอนตัวออกจากโครงการวิจัยได้ทุกเมื่อ โดยไม่กระทบต่อการดูแลรักษาที่พึงได้รับตามปกติ

ท่านมีสิทธิที่จะถอนตัวหรือบอกเลิกการเข้าร่วมโครงการวิจัยได้ทุกเมื่อ โดยไม่มีผลกระทบใดๆ ต่อแผนการรักษาและบริการที่ทารกของท่านพึงได้รับตามปกติจากทางโรงพยาบาล

9. ชื่อ ที่อยู่และเบอร์โทรศัพท์ของผู้วิจัยที่ผู้ยินยอมคนให้ทำการวิจัยสามารถติดต่อได้โดยสะดวก ทั้งในและนอกเวลาราชการ กรณีมีเหตุจำเป็นหรือฉุกเฉิน

นางศรีสุรีย์ สุนพยานนท์

โรงพยาบาลพระนครศรีอยุธยา

ต. ประตู่ชัย อ. พระนครศรีอยุธยา

จ. พระนครศรีอยุธยา 13000

หมายเลขโทรศัพท์ที่สามารถติดต่อได้ 01- 3761088

10. ข้อพิจารณาด้านจริยธรรม (ethical consideration)

การวิจัยครั้งนี้ เป็นการศึกษาถึงทดลอง เกี่ยวกับการจัดท่านนอนต่อระดับของออกซิเจน อัตราการเต้นของหัวใจ และอัตราการหายใจของทารก ซึ่งผู้วิจัยจะใช้ความระมัดระวังดูแลตามหลักการที่ถูกต้อง และเฝ้าระวังอย่างใกล้ชิด เพื่อป้องกันความเสี่ยงที่อาจจะเกิดขึ้นในระหว่างที่มีการจัดท่านนอน

ในการวิจัย หากท่านรู้สึกกังวลใจหรือไม่พร้อมที่จะให้ทารกของท่านเข้าร่วมการวิจัยครั้งนี้ ผู้วิจัยยินดีที่จะอธิบายและแสดงการจัดท่านนอนให้ท่านดูก่อนที่จะทำการวิจัย เพื่อความสบายใจของท่าน แต่ถ้าท่านยังไม่สบายใจ ผู้วิจัยจะหยุดดำเนินกิจกรรม และรายงานให้พยาบาลผู้ดูแลได้รับทราบเพื่อให้การดูแลทารกตามปกติต่อไป

ข้อมูลต่างๆ ที่ได้จากการวิจัย ผู้วิจัยจะเก็บเป็นความลับ ผลการวิจัยจะเสนอในภาพรวมจะไม่เปิดเผยชื่อ นามสกุล ของทารกท่านให้ผู้อื่นทราบ

ศรีสุรีย์ สุนพยานนท์

ผู้วิจัย

ใบแสดงเจตนา ยินยอมเข้าร่วมโครงการวิจัยทางการแพทย์ (Inform Consent)

การวิจัยเรื่อง ผลของการจัดทำนอนต่อค่าความอิมตัวของออกซิเจน สัญญาณชีพ และระยะเวลาในการหย่าเครื่องช่วยหายใจของทารกเกิดก่อนกำหนดขณะหย่าเครื่องช่วยหายใจ

วันที่ เดือน..... พ.ศ.....

ข้าพเจ้า.....มีความเกี่ยวข้องกับ.....

.....โดยเป็น.....ขอแสดงความยินยอมให้.....

.....เข้าร่วมโครงการวิจัย ซึ่งก่อนที่จะลงนามยินยอม ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย อันตรายหรืออาการที่อาจจะเกิดขึ้นจากการวิจัย รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียดและมีความเข้าใจเป็นอย่างดี ซึ่งรายละเอียดและขั้นตอนที่ทารกเข้าร่วมโครงการจะได้รับการปฏิบัติ ดังรายละเอียดในเอกสารชี้แจงข้อมูล ซึ่งผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจ ไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ

ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้ด้วยความสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลต่อการรักษาโรคของทารกของข้าพเจ้าที่พึงจะได้รับต่อไป ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับทารกของข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่สรุปเป็นผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับทารกของข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีที่เป็นด้วยเหตุผลทางวิชาการเท่านั้น ผู้วิจัยรับรองว่าจะใช้ความระมัดระวังตามหลักการที่ถูกต้องในการปกป้องคุ้มครองต่อผลดลมคอของทารกในขณะที่จัดทำนอน จึงไม่มีอันตรายกับทารก แต่หากเกิดอันตรายใดๆ อันเนื่องจากการวิจัยดังกล่าว ผู้วิจัยจะหยุดดำเนินการวิจัย และรายงานแพทย์ร่วมกับแก้ไขทารกทันที ผู้วิจัยรับรองว่าหากมีข้อมูลเพิ่มเติมที่ส่งผลกระทบต่อการศึกษา ข้าพเจ้าจะได้รับแจ้งให้ทราบโดยที่ไม่มีปิดบังซ่อนเร้น

ข้าพเจ้าได้อ่านข้อความข้างต้นแล้ว และมีความเข้าใจดีทุกประการ และยินยอมให้ทารกของข้าพเจ้าเข้าร่วมโครงการวิจัยดังกล่าวด้วยความเต็มใจ

ลงนาม (ผู้ยินยอม)

(.....)

ลงนาม (พยาน)

(.....)

ลงนาม (พยาน)

(.....)

APPENDIX C

แบบบันทึกข้อมูลส่วนบุคคล โครงการวิจัย เรื่อง ผลของการจัดทำนอนต่อค่าความอิ่มตัวของ ออกซิเจน อัตราการเต้นของหัวใจ อัตราการหายใจ และระยะเวลาในการหย่าเครื่องช่วยหายใจของ ทารกเกิดก่อนกำหนดขณะหย่าเครื่องช่วยหายใจ

ส่วนที่ 1. ข้อมูลส่วนบุคคลของทารก

ทารกชายที่.....วันที่ศึกษา.....

วันที่ใช้เครื่องช่วยหายใจ..... เวลา

วันที่เริ่มหย่าเครื่องช่วยหายใจ..... เวลา

วันที่ถอดท่อช่วยหายใจ..... เวลา

ชื่อทารก เพศ..... อายุ... วัน มารดาอายุ.....ปี

อายุครรภ์..... สัปดาห์ น้ำหนักแรกเกิด.....กรัม น้ำหนักปัจจุบัน.....กรัม

วิธีคลอด.....การวินิจฉัย.....H.N.

การรักษาและยาที่ได้รับ.....

Mechanical ventilation setting ณ วันที่ศึกษา.....

Condition ของทารกก่อนหย่าเครื่องช่วยหายใจ.....

SpO₂ HR =bpm. RR = bpm.

Condition ของทารกหลังหย่าเครื่องช่วยหายใจครั้งแรก.....

SpO₂ HR =bpm. RR = bpm.

Condition ของทารกหลังถอดท่อช่วยหายใจเครื่องช่วยหายใจ.....

SpO₂ HR =bpm. RR = bpm.

หมายเหตุ

.....

.....

BIOGRAPHY

NAME	Mrs. Srisuree Soonpayanon
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