Effectiveness of an Endotracheal Tube Adjustable Stabilizing Set to Prevent Unplanned Extubation in Preterm Infants: A Quasi-experimental Study

Aungsumalin Sangngam, Jutamas Chotibang, Patcharee Woragidpoonpol*

Abstract: Preterm infants born before 34 weeks of gestation often face respiratory challenges and may require resuscitation with an endotracheal tube and ventilator support. Unplanned extubation is a common problem for such infants, affecting their care and outcomes. This quasi-experimental study compared the incidence of unplanned extubation, stability of vital signs and oxygen saturation between a control group (n = 24) receiving routine care in a neonatal intensive care unit and an experimental group (n = 24) receiving routine care along with the use of the Endotracheal Tube Adjustable Stabilizing Set, developed by the researchers. The latter set comprises an endotracheal tube-holding cap, head-locked pillows, and an oxygen meter. Data were analyzed using descriptive statistics, t-tests, chi-square tests, and Fisher's exact tests.

Results show that the control group had an average tracheal tube insertion time of 78.94 hours, while the experimental group had an average of 39.35 hours. The incidence of unplanned extubation was 33.33% (8 cases) in the control group and 4.17% (1 case) in the experimental group. The unplanned extubation rate per 100 ventilator days was 4.41 times in the experimental group, significantly less than in the control group (23.84 times). The experimental group also exhibited significantly more time spent on vital signs and oxygen saturation within normal limits than the control group. In conclusion, using the Endotracheal Tube Adjustable Stabilizing Set in neonatal care can improve patient outcomes by reducing the incidence of unplanned extubation and stabilizing vital signs. This set has passed patentability evaluation for product design and enhances neonatal care by stabilizing endotracheal tubes, reducing slippage, and helping nurses provide more effective care. However, further testing in different settings with larger sample sizes and an equal average tracheal tube insertion time between the two groups is recommended to validate these findings.

Keywords: Adjustable stabilizing set, Endotracheal tube, Neonatal intensive care unit, Oxygen saturation, Preterm infants, Unplanned extubation, Vital signs

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***Aungsumalin Sangngam**, RN, Graduate student of Nursing Science Program in Pediatric Nursing, Faculty of Nursing, Chiang Mai University, Chiang Mai, Thailand. E-mail: Aungsumalin_s@cmu.ac.th*

***Correspondence to: Jutamas Chotibang**,*RN, PhD, Associate Professor, Faculty of Nursing, Chiang Mai University, Chiang Mai, Thailand. E-mail: jutamas.c@cmu.ac.th*

***Patcharee Woragidpoonpol**, RN, PhD, Associate Professor, Faculty of Nursing, Chiang Mai University, Chiang Mai, Thailand. E-mail: patcharee.w@cmu.ac.th*

Introduction

Respiratory disorders are the most common cause of admission to neonatal intensive care units (NICUs).[1-2] Medical treatment for newborns has developed according to advances in care in NICUs,[3] but respiratory disorders remain a major cause of neonatal mortality and morbidity.[4-7] Preterm infants with a gestational age below 37 weeks often experience respiratory problems, which are the leading cause of prolonged length of stay in NICUs and death in preterm.[1,3,7-11]

Globally, it was estimated that in 2020, of around 13.4 million newborns, 9.9% were preterm.[12] In Thailand, the average percentage of preterm births for infants weighing less than 2,500 grams ranged from 9.52% to 9.74% between 2020 and 2023.[13] Preterm infants face a significantly higher risk of

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chronic health problems and mortality compared to term infants, with their risk of death being two to three times greater.[14-15]

Endotracheal intubation, while crucial for the survival of these infants, can cause significant physiological stress and pain, increasing the risk of unplanned extubation (UE).[16] UE is a serious issue in NICUs, with reported rates ranging from 3.4% to 16.6%, leading to potential adverse outcomes such as hypoxemia, bradycardia, ventilator-associated pneumonia, and increased mortality.[16,18] Major risk factors for UE include inadequate endotracheal tube securement, agitation, and infant movement.[17] To address this, the researchers recognized a critical need for an innovative solution to overcome these problems. They developed the Endotracheal Tube Adjustable Stabilizing Set (ET-ASS) to reduce the incidence of UE and improve outcomes for preterm infants requiring intubation and ventilation. This article reports on a study evaluating the effectiveness of the ET-ASS in a clinical setting to provide evidence for its potential to enhance the safety of neonatal care.

Literature Review and Conceptual Framework

Most cases of slippage of the endotracheal tube occur on average in infants at 30-36 weeks gestational age.[18-19] At this stage, UE is more prevalent due to the critical developmental phase of various physiological systems, resulting in heightened muscle tone and increased sensitivity to pain.[18-21] Although infants at this gestational age exhibit improved motor control compared to their younger counterparts, they may still experience movement and restlessness, which can elevate the risk of tracheal tube displacement.[20-21] Moreover, the duration of tube insertion correlates with an increased probability of tube detachment.[22] The most common causes of UE are restlessness, caused by discomfort or pain (30.8%), and improper tube fixation and/or positioning (17.9%).[16] In some cases, used adhesives are left unchanged or fresh adhesive is applied on top of the old, causing decreased endotracheal tube-holding (16.6%).[16,18-19] Nurses may also lack training in lung percussion, sputum suction, blood drawing, x-ray photography, and physical handling of infants.[16,21,23] Altered or incorrect sleeping positions causing friction against the tracheal tube are responsible for 1.3% of cases, while in 2.6% of cases, the cause is unknown.[16] Effects on preterm infants of UE may include metabolic acidosis, heart failure, hypoxia, pneumonia, delayed development, and irregular vital signs including heart rate, respiratory rate, and blood oxygen saturation, resulting in longer intubation times and hospital stays.[18,21-24]

Previous studies have been conducted on the prevention of UE. Several methods are available, such as endotracheal tube fixation devices, friction reduction devices, and muscle relaxants and sedatives administration.[16,21,25] Innovations or devices exclusively for endotracheal tube fixation to reduce the occurrence of slippage include (1) "Neo safe" fixation devices, which fix only the endotracheal tube, with no ventilator or circuit attachments;[26] (2) the "Happy Bridge," which causes skin irritation and abrasions when infants move, while being difficult to use and having a relatively high production cost;[27] (3) the "Logan Bow," which is a small, easy-to-use device attached by an adhesive bandage to the ear but the adhesive must be replaced as it becomes soiled, causing irritation and abrasions on the cheek. The device is made of solid wire, which can cause pressure sores with prolonged use;[28] and (4) the "NeoBar," which provides stable fixation but does not address all the risk factors of UE.[29]

Innovations or devices specifically designed for reducing friction on the endotracheal tube and providing neck support include: (1) the "T-model" by which the endotracheal tube cannot be fixed, resulting in an inability to position an infant to align the head and neck with the body midline;[30] (2) the infant head-lock pillow, made from upholstery fabric,

which causes heating and dampness from perspiration when used for extended periods in the same position;[31] and (3) muscle relaxants and sedatives.[16,18] A contemporary study has yet to be conducted regarding the effects of such drugs on preterm infants. However, previous studies report the administration of drugs to infants to induce sleep or reduce restlessness, including morphine, benzodiazepines, and phenobarbital.[18-21]

Previous studies report occurrences of UE and duration of intubation only, without reporting on the vital sign responses of preterm infants. A common problem with UE in critically ill infants is that reinserting the tube causes several serious complications. Previous research described above has demonstrated the importance of secure ET fixation and resulted in the potential for new devices to improve patient outcomes. The primary investigator (PI) has developed guidelines to prevent UE and developed the integrated Endotracheal Tube Adjustable Stabilizing Set (ET-ASS). This Set consists of (1) an endotracheal tube-holding cap, which secures the tracheal tube and prevents tension if the infant struggles or shakes its head, and (2) a head-lock pillow, which facilitates appropriate sleeping position. Studies found that the prone sleeping position increases blood oxygen saturation in preterm infants, but only for a short time and with a high risk of UE and possible long-term consequences.[22-23,31] In contrast, the supine position, with head and neck aligned with the body midline, provides the most appropriate sleeping position for preterm infants with endotracheal tubes. The supine position increases blood oxygen saturation,[31-32] providing an adequate supply of oxygen while helping to reduce stress caused by bodily movement. Reduced movement helps maintain a slow and steady heart rate, requiring less energy and oxygen, resulting in improved vital sign response.[32,34]

This study recorded occurrences of UE and vital sign response of preterm infants, according to Als' Synactive Theory of Development.[33-34] This theory describes changes to infant physiology and behavior in response to stimuli and interaction with the environment and consists of five subsystems. When an infant's five subsystems are stressed, the sensory system is stimulated excessively. In the case of respiratory problems requiring intubation due to undeveloped lungs, infant restlessness and struggle can cause UE, affecting a stress response in all five subsystems and sensory overstimulation. The infant then experiences physiological expressions or changes, such as increased heart and respiratory rates and decreased blood oxygen saturation.[31-34]

The ET-ASS addresses the pain points of previous innovations by providing a secure, stable, and comfortable solution for preterm infants requiring intubation. By minimizing the risk factors associated with UE, the ET-ASS has the potential to improve outcomes in the NICU significantly. In conclusion, the development of the ET-ASS represents a significant advancement in neonatal care. It offers a comprehensive solution to prevent UE by addressing the critical risk factors and providing stable ET fixation. However, further studies are needed to validate its effectiveness in different clinical settings and larger populations.

Study Aim

This study aimed to compare the incidence of unplanned extubation, vital signs stability, and oxygen saturation in the experimental group of preterm infants in NICU using the ET-ASS with that of the control group, which received only routine care.

Methods

Design: This study was quasi-experimental research with two groups, and this report followed the Transparent Reporting of Evaluation with Nonrandomized Design (TREND) Statement.

Sample and Setting: The sample consisted of 48 preterm infants admitted to the NICU in a provincial hospital in northern Thailand. The NICU at this hospital

can accommodate infants from birth up to seven days old. Most of the infants were preterm with respiratory system problems. The total number of beds available for infant care was 16 beds. All infants received routine care to prevent UE throughout the study, but infants in the experimental group received the ET-ASS, consisting of the endotracheal tube-holding cap and the head-locked pillows. A significance level of .05, with an estimated effect size of .76 and power of .80 based on the results from a previous study,[26,35] was set. According to our calculation, the total sample size was 46, with 23 in each group. To compensate for possible incomplete data and loss of participants, we added 5% to the sample size.[36] Therefore, the final sample size was 24 per group, totaling 48 participants. Purposive sampling was used to select preterm infants according to the inclusion criteria, then they were randomly assigned to the experimental or control group until 24 infants were in each group. Inclusion criteria included being preterm infants: 1) 30-36 weeks gestational age; 2) requiring tracheal tubes and ventilation; 3) without abnormal conditions at birth, including congenital heart disease or chromosome abnormalities, and no further complications such as intolerance to breastfeeding or necrotizing enterocolitis (NEC); and 4) parental consent by written letter was given for infants to participate in the study. Exclusion criteria were preterm infants: 1) exhibiting changing symptoms and/or critical conditions requiring immediate assistance during the research process, such as septic shock and cardiac arrest; 2) having jaundice requiring phototherapy; or 3) requiring sedative treatment and pain management. Termination criteria were preterm infants: 1) requiring transfer to another hospital for treatment; 2) requiring emergency surgery, for example, due to intestinal gangrene or hypertrophic coronary artery disease; 3) dying during the study; and 4) exhibiting a drastic change of health or discomfort for an indeterminate reason, upon which required the ET-ASS be discontinued immediately, the sample removed from the experimental group, and recorded sample data excluded from further study. In this study, no infants were excluded or terminated.

Ethical Considerations: Study approval was given by the Research Ethics Review Committee, Faculty of Nursing, Chiang Mai University (ID 052/2566), and the ethics committee of the study hospital (EC CRH 064/66 Ex). All parents were informed regarding the study's objectives, procedures, potential risks and benefits, voluntary participation, protection of confidentiality and the right to withdraw at any point in the study without consequence to current treatment or hospital service. Before signing the informed consent form, parents were assured of confidentiality and anonymity and provided adequate time to ask questions about the study. Throughout the study, the assigned nurse remained with the infants continuously. If any infant displayed abnormal signs or symptoms, including respiratory distress, desaturation, hypertension, or any sudden and unexplained deterioration in health or discomfort, they would be promptly withdrawn from the study. Immediate care would be provided, which might involve re-positioning, adjusting respiration, suctioning, or removing the ET-ASS, to address the issue. In this study, no such events occurred. Additionally, due to COVID-19, researchers were required to disinfect their hands before and after handling an infant, wear a hygienic mask, and maintain a distance from others of at least 1-2 metres.

Research Instruments included three data collection forms developed by the PI and the intervention instrument, the ET-ASS. These comprised as follows:

The Newborn General Information Record Form collects data on gender, postnatal age, birth weight, diagnosis, chronological age, weight, and admission date.

The Unplanned Extubation Record Form assesses tracheal tube displacement, including the date of tracheal tube insertion, size and depth of the tracheal tube, date of tracheal tube removal, and number of times the tracheal tube was inserted. The form also recorded the duration of endotracheal intubation,

measured in hours and minutes from initial insertion to successful removal by the attending physician. Any reinsertions due to tube dislodgement did not interrupt this continuous count until final removal. Additionally, reasons for tracheal tube displacement could be assessed based on signs or symptoms such as crying or vocalization by the infant, a sudden rise in subcutaneous emphysema around the tracheal tube, uneven chest movement on both sides or asymmetrical breath sounds heard at the axilla (underarm) on both sides. The PI who provided nursing care to both groups assessed these factors during all shifts: morning shift at 07:50 A.M., afternoon shift at 03:50 P.M., and night shift at 11:50 P.M.

The Vital Signs Record Form assessed autonomic nervous system responsiveness and included blood oxygen saturation level, heart rate (beats per minute), and respiratory rate (breaths per minute). Data were recorded every hour from the day the tracheal tube was inserted until the last removal before discharge from the NICU. The normal range for these parameters in preterm newborns is a heart rate of 110-160 beats per minute, blood oxygen saturation of 90-95%, and respiratory rate of 40-60 breaths per minute. These values were assessed using a pulse oximeter.

Validity testing: All data collection forms underwent content validation by six experts, including a neonatologist, two pediatric lecturers, two advanced practice neonatal nurses, and a neonatal nurse. The content validity index (CVI) for the tracheal tube slippage record achieved a score of .85. The accuracy of the pulse oximeter model "Life Scope" was standardized and tested by the manufacturer every year.

The PI and assistants performed availability tests before every recording according to the device's operating instructions. A sensor probe device, which emits a red light when it comes into contact with the body, displayed graphs and the number of vital signs on the screen.

Reliability testing: The inter-rater reliability of the data collection forms for recording UE was assessed for use by the PI and three assistants. These assistants were professional nurses with over five years of experience in NICUs and trained in research ethics. The first data collection stage was developed through a pilot study by observing the symptoms and signs of the incident during UE from a recorded videotape of five preterm infants, mirroring the conditions of the study's experimental group. The consistency of these observations was quantified through the calculation of the inter-rater reliability coefficient, resulting in a reliability index of .87. This index surpassed the acceptable threshold for a correlation coefficient, which is greater than .80.[37]

Endotracheal Tube Adjustable Stabilizing Set (ET-ASS) development and implementation: The ET-ASS was adjusted to the appropriate size for infants in each weight range sizes S-XL, and included a user manual and endotracheal tube-holding cap (**Figure 1**). It is made of knitted yarn to accommodate different infant head sizes according to age and was designed by the PI with two long straps running from both temples, the ends of which have hard connectors for attachment to the breathing device and a chin strap to prevent the cap slipping if the infant moved, to reduce tension on the endotracheal tube. Head-lock pillows (**Figure 2**) are infant neck-support pillows made from natural cotton, which are inexpensive, comfortable, and provide good ventilation and insulation while being easy to clean. An adjustable sliding strap connects the two parallel cushions, with a hook and loop built to adjust according to the infant's neck size. Synthetic polyester fiber was used as the filling material due to its flexibility properties while retaining shape well and demonstrating good heat dissipation. Synthetic polyester can withstand temperatures as high as 259 degrees Celsius, and this property allows the fibers to change shape and help stabilize a sleeping infant's head in an incubator. The pulse oximeter "Life Scope Model" is the machine that Thai hospitals use to measure heart rate, respiratory rate, and blood oxygen saturation using sensor probe cables. Infants in the experimental group received the same routine care with the ET-ASS.

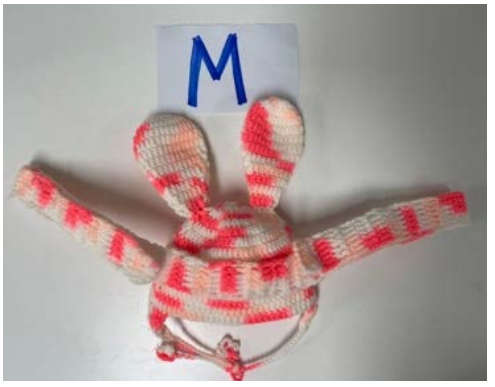

Figure 1. Endotracheal tube-holding cap size M for BW ≥ 2,000 gms

Figure 2. Head-locked pillows size S for BW ≥ 1,000 gms

Figure 3. The adjustable endotracheal tube

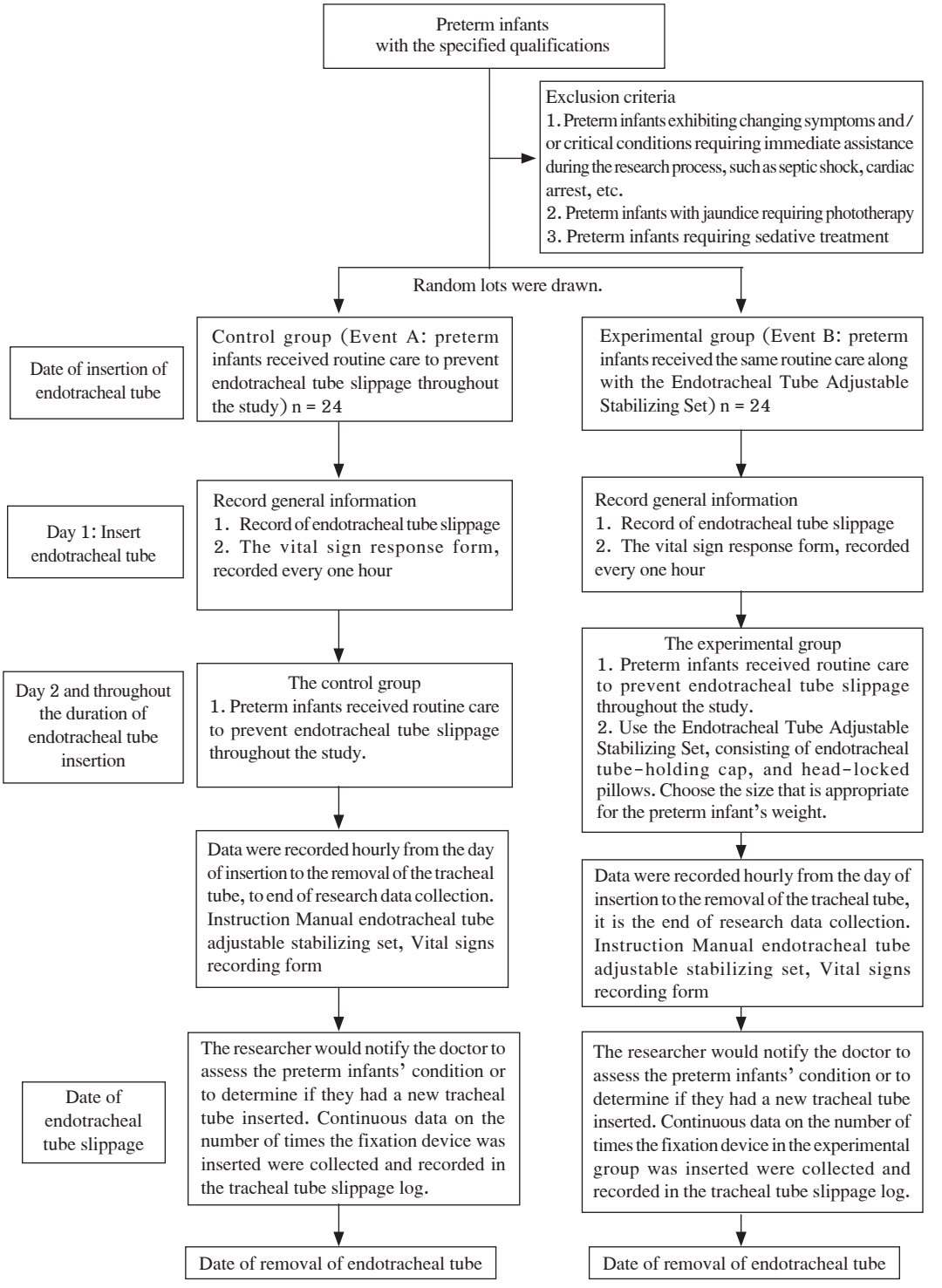

Figure 4. Flow chart of study

Routine Care was given to prevent UE, including: 1) checking the depth and position of the tracheal tube according to the size and depth at the incubator fixed display label, any change in size or position is recorded during the transfer periods on the morning shift (07:50 A.M.), afternoon shift (03:50 P.M.), and night shift (11:50 P.M.); 2) replacing the tracheal tube adhesive bandage occasionally or when adhesive begins to weaken; 3) suction of phlegm in the tracheal tube by two practitioners and monitoring of obstructed tracheal tube; 4) preterm infants sleep in a nest; 5) maintaining comfort and dryness of preterm infants with ready-made diapers; 6) arranging the environment to reduce light by covering the incubator cabinet; 7) watching for signs that indicate UE: 1) preterm infant made sounds or cries, 2) chest moved unevenly on both sides or did not move according to the operation of the ventilator, 3) heart rate increased or decreased more than usual, increased respiratory rate or respiratory conditions, blood oxygen saturation decrease drastically, 4) decreased breathing sound, or 5) insertion of the secretion suction tube in the tracheal tube down to the stomach.

Data Collection: After study approval, the PI requested the NICU head nurse to obtain three research assistants (RAs), all registered nurses working in the NICU of the studied hospital, to receive comprehensive training from the PI. First, the PI surveyed preterm infants intubated and ventilated in the NICU. Next, all researchers obtained the visiting times of parents to explain the objectives, data collection procedures, and protection of the human rights of participants to the parents. Finally, on agreeing to participate in the study, parents were asked to sign a consent form before commencing, with requested permission from the physicians responsible for treating the infants. Once granted permission, all researchers studied the medical history data and collected general information from both sample groups. The experimental group received the ET-ASS, available in sizes S-XL according to the infant's weight. Observation and information regarding UE were recorded on the general data forms at every shift, with vital signs recorded hourly, from the moment of insertion of the endotracheal tube to removal.

For both groups, the PI or RAs notified the physician if the infant had a new endotracheal tube inserted, continuous data were collected and recorded on the UE regarding the number of occurrences, together with re-application of the holding device in the experimental group, from study commencement to conclusion.

Data Analysis: Data were analyzed using statistical software, Stata version 16.0. The t-test assumptions of normality and homogeneity of variance were assessed, comparing the means of the dependent variables. The Kolmogorov-Smirnov test results indicated that the dependent variables were normally distributed. The sample's general information was analyzed using descriptive statistics, including frequency distribution, percentage, mean, and standard deviation. The number of times that heart rate, respiratory rate, and oxygen saturation deviated from the normal range was compared between the control and experimental groups and analyzed using frequency distribution, percentage, mean, and standard deviation. An independent t-test was used to compare continuous variables between the experimental and control groups. The Chi-square test and Fisher's exact test were used to identify the significant difference in categorical variables between the experimental and control groups. A p-value of .05 was considered statistically significant. The UE rate per 100 ventilator days was calculated by dividing the number of endotracheal slippages by the number of ventilator days and multiplying the result by 100 (ventilator days).[38]

Results

All baseline characteristics were similar between the two groups, except for the duration of tube insertion, which differed significantly. The control group had an average tube insertion time of 78.94 hours compared to 39.35 hours in the experimental group ($p < .001$) (see **Table 1**).

Table 1. Baseline characteristics and descriptive statistics for control and experimental groups

Characteristics	Control group (n = 24)		Experimental group (n = 24)		p-value
	n	%	n	%	
Gender					
Male	11	45.83	11	45.83	1.000*
Female	13	54.17	13	54.17	
Gestational age (weeks)					
< 33	6	25.00	8	33.33	.525**
33-36	18	75.00	16	66.67	
Mean (± SD)	33.68	(±1.58)	33.58	(±1.67)	.930***
Birth weight (grams)					
1,000-1,499	3	12.5	2	8.33	.510**
1,500-1,999	11	45.83	15	62.50	
2,000-2,499	10	41.67	7	29.17	
Mean (± SD)	1,897.67	(± 244.14)	1,867.54	(± 232.93)	.664***
Birth weight on day of study (grams)					
1,000-1,499	3	12.50	2	8.33	.510**
1,500-1,999	11	45.83	15	62.50	
2,000-2,499	10	41.67	7	29.17	
Mean (±S.D.)	1,893.50	(± 256.57)	1,859.13	(± 254.78)	.644***
Diagnosis					
Respiratory distress syndrome	9	37.50	10	41.67	.988**
Transient tachypnea	7	29.17	6	25.00	
Respiratory distress	5	20.83	5	20.83	
Birth asphyxia	3	12.50	3	12.50	
Diameter of endotracheal tube (millimeters)					
3.5	15	62.50	16	66.67	.763**
3.0	9	37.50	8	33.33	
2.5	0	0.00	0	0.00	
Length of endotracheal tube (millimeters)					
7.0	9	37.50	10	41.67	.789**
7.5	1	4.17	0	0.00	
8.0	8	33.33	8	33.33	
8.5	6	25.00	6	25.00	
Duration of endotracheal tube insertion (hours)					
Mean (± SD)	78.94 (± 14.70)		39.35 (± 17.20)		< .001***
Range	11-104		22-101		

Note. * Chi-square test, ** Fisher's exact test, *** Independent t-test, p < .05

Table 2 shows the cause of tracheal tube slippage, which occurred predominantly in the control group, and most frequently included pulling on the ventilator pipe and behaviors, such as infants struggling, showing restlessness, or crying. Loud crying was the primary indication of tracheal tube slippage. In the control group, 75% of the infants (6 out of 8) exhibited restlessness. Before the occurrence of tracheal tube slippage, mucus suctioning was performed in 62.50% of cases. All preterm infants were equipped with an orogastric (OG) tube. Following slippage, reinsertion of the tracheal tube was necessary for both groups.

Table 2. Distribution and percentage of the sample by causes, signs, symptoms, and behaviors prior to endotracheal tube slippage, and reinsertion after slippage

Characteristics	Control group (n = 24)		Experimental group (n = 24)	
	n	%*	n	%*
Cause of endotracheal tube slippage				
Pulling on ventilator pipe**	8	100.00	0	0.00
Infant struggle/restlessness**	8	100.00	1	100.00
Infant crying**	8	100.00	1	100.00
Adhesive degraded**	2	25.00	0	0.00
Excess mucus/saliva	1	12.50	1	100.00
Infant movement	0	0.00	0	0.00
Infant vomiting	0	0.00	0	0.00
Infant signs/symptoms				
Crying**	8	100.00	1	100.00
Gastric fluid rising into trachea**	4	50.00	0	0.00
Axilla produces uneven sound on both sides**	4	50.00	1	100.00
Chest produces uneven sound on both sides	4	50.00	1	100.00
Infant behavioral characteristics				
Restlessness**	6	75.00	1	100.00
Crying**	2	25.00	0	0.00
Procedures performed on infants before tracheal tube slippage				
Mucus/sputum suction**	5	62.50	0	0.00
Blood drawing**	2	25.00	0	0.00
Intravenous fluid injection	1	12.50	1	100.00
Orogastric tube insertion	0	0.00	0	0.00
Lumbar puncture	0	0.00	0	0.00
Apparatus provided to infants during tracheal tube slippage				
Orogastric tube**	8	100.00	1	100.00
Umbilical vein catheter/umbilical artery catheter**	7	87.50	0	0.00
Peripheral intravenous line	1	12.50	1	100.00
Reinsertion of tracheal tube after slippage	8	100.00	1	100.00

Note. * Number and percentage calculated from the number of tracheal tube slippages, control group 8 cases and experimental group 1 case.

** Single group sample, many possible causes

Table 3 presents the occurrences of UE among preterm infants, showing a rate of 33.33% or 8 cases in the control group, compared to 4.17% or 1 case in the experimental group. The experimental group experienced significantly fewer instances of UE ($p = .01$). The rate of UE per 100 ventilator days was 4.41 in the experiment group, significantly lower than the 23.84 times observed in the control group.

Table 3. Comparison of endotracheal tube slippage rates and incidences per 100 ventilator days of insertion between control and experimental groups

Characteristics	Control group (n = 24)		Experimental group (n = 24)		χ^2 (p-value)
	n	%	n	%	
Endotracheal tube					
Slippage	8	33.33	1	4.17	6.71 (0.010)*
Not slippage	16	66.67	23	95.83	
Tracheal tube slippage occurrences per 100 ventilator days		23.84		4.41	

Note. * Chi-square test

Table 4 compares the percentage of time that vital signs remained within normal ranges between the control and experimental groups, demonstrating that the experimental group significantly outperformed the control group in maintaining normal blood oxygen saturation (99.48% vs. 89.23%), heart rate (91.60% vs. 81.43%), and respiratory rate (96.17% vs. 86.31%), with p-values less than .001 across these measures. This indicates that the intervention used in the experimental group was effective in stabilizing vital signs, suggesting improved clinical outcomes for these infants.

Table 4. Comparative analysis of vital sign stability between control and experimental groups in preterm infants

Characteristics	Control group (n = 24)		Experimental group (n = 24)		p-value
	number of times spent	%	number of times spent	%	
Blood oxygen saturation level					
Normal (90-95%)	1,624	89.23	1,343	99.48	< .001*
Abnormal (< 90%)	196	10.77	7	0.52	
Average (± SD)	95.72	(± 3.86)	97.89	(± 1.75)	< .001**
Heart rate					
Normal (110-160 bpm)	1,083	81.43	1,724	91.60	< .001*
Abnormal (> 160 bpm)	247	18.57	158	8.40	
Average (± SD)	152.61	(± 10.12)	134.64	(± 15.69)	< .001**
Respiratory rate					
Normal (40-60bpm)	1,147	86.31	1,810	96.17	< .001*
Abnormal (> 60bpm)	182	13.69	72	3.83	
Average (± SD)	53.14	(± 7.30)	45.00	(± 6.49)	< .001**

Note. * Chi-square test, ** Independent t-test

Discussion

The findings of this study suggested the potential effectiveness of the ET-ASS in reducing the incidence of UE, maintaining more stable vital signs, and improving oxygen saturation levels in preterm infants. The occurrence of UE per 100 ventilator days of insertion was significantly lower in the experimental group (4.41 times) compared to the control group (23.84 times). This rate, however, was higher than that reported in previous international studies, which noted UE rates ranging from 0.14 to 5.3 times per

100 days.[16] The variability in UE rates between our study and previous studies could stem from several factors, including differences in NICU practices, clinical protocols, or the populations studied. Our study may have involved a more diverse or severely ill preterm infant cohort, with greater instances of respiratory distress or other complications, potentially leading to increased UE due to frequent handling and medical interventions. Previous research documents lower UE rates, possibly focusing on older or more stable preterm populations.[26] Additionally, differences in nurse-to-patient ratios and varying levels of nurse training could affect care quality and the frequency of endotracheal tube monitoring and securing. Another study also highlighted how staffing patterns and nurse competencies might influence UE rates.[39] These operational and methodological differences likely contribute to the higher UE rates observed in our study and point to areas for further investigation.

In this study, the ET-ASS significantly enhanced neonatal respiratory care for preterm infants by reducing UE and stabilizing vital signs and oxygen saturations. The ET-ASS incorporates a tube-holding cap made from knitted yarn, designed to adapt to various infant head sizes, and features long straps with hard connectors and a chin strap to secure it. This mechanical stabilization was crucial in neonatal care, as even slight movements could dislodge a tube, compromising the airway and leading to potential oxygenation drops. The ET-ASS included head-lock pillows made from natural cotton, designed to support the infant's neck and maintain alignment with the respiratory apparatus. An adjustable sliding strap with a built-in hook and loop system allowed customization to fit the different neck sizes, enhancing positional stability and maintaining an open airway, facilitating consistent airflow and reducing the risk of positional asphyxia. By securing the endotracheal tube and optimizing the positioning of the infant's head and neck, the ET-ASS ensured effective ventilation and maximized oxygen delivery, as evidenced by improved oxygen saturation levels monitored by pulse oximetry. This comprehensive approach aligns with previous studies,[26] demonstrating the efficacy of wire support structures and specific positioning strategies. The ET-ASS's innovative design significantly reduces the need for frequent reintubations, which pose risks of trauma, infection, and fluctuations in vital signs. By minimizing these events, the ET-ASS contributed to more stable vital signs and overall improved clinical outcomes. A study has described a safety holder device for securing endotracheal tubes in neonates, sharing the ET-ASS's objectives of reducing UE and enhancing stability.[40] The model used advanced computer-aided design and 3D printing, effectively preventing a tube from dislodging through robust support and adjustable features.[40] However, the reliance on sophisticated equipment can restrict its practical application, especially in settings with limited resources. In contrast, the ET-ASS, priced at about US$ 4 per set, offers a cost-effective and simpler solution, promoting broader implementation and accessibility in neonatal care, particularly in under-resourced environments. This integration of mechanical and positional stability tools represents a novel advancement in neonatal care, highlighting the importance of tailored interventions to enhance treatment outcomes for preterm infants requiring respiratory support.

Limitations

Some limitations of this study must be addressed. Firstly, factors in the clinical practice could not be controlled, such as x-ray imaging, changing clothes, airway obstruction, folding or bending of tracheal tubes and water in the ventilator circuit, all of which could affect the UE of tracheal tubes. Secondly, this study collected data during the UE of the endotracheal tube, including situations such as mucus/sputum suction, blood drawing, intravenous fluid

injection, an orogastric tube insertion, lumbar puncture, or UVC (UVC/UAC), all of which caused UE. However, data regarding the frequency or duration of these procedures were not recorded. Thirdly, data were not recorded regarding the frequency or duration of procedures and the amount of secretion during suction that caused UE.

Recommendations for Future Research

Other factors related to UE should be studied in preterm infants. The Cox proportional hazards regression test should be used to clearly and more reliably analyze the study results of the incidence of tracheal duct dislocation and duration of tracheal duct insertion.

Furthermore, in our study, the duration of tube insertion differed significantly between the groups, with the control group averaging 78.94 hours and the experimental group at 39.35 hours. This significant difference in the duration of tube insertion between the groups underscores the impact of tube stability on the overall treatment timeline and the weaning process and highlights the potential benefits of the ET-ASS in maintaining tube position, thereby minimizing the need for reinsertion and allowing a more continuous and potentially shorter weaning process. To address this, future studies should control illness severity to ensure more accurate assessments of intervention effectiveness. Moreover, the discrepancy in duration largely resulted from operational procedures within the NICU. In the control group, tube dislodgement required reverting from weaning to more supportive ventilator settings, necessitating a restart of the weaning process. This not only prolonged intubation but also highlighted the impact of procedural management on study outcomes. Future research should standardize care processes and explore ways to minimize reintubation, thereby ensuring consistent and comparable conditions across study groups.

Conclusion and Implications for Nursing Practice

The ET-ASS seems to reduce UE and maintain a normal range of heart and respiratory rates and oxygen saturation among premature infants with endotracheal intubation. However, nurses should use caution when combining the ET-ASS with nesting equipment for older infants, as this may inadvertently displace the tube due to infant movements during nesting adaptation.

Declaration of competing interests: The authors declared no conflicts of interest.

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ประสิทธิภาพของชุดอุปกรณ์ปรับความคงที่ของท่อช่วยหายใจเลื่อนหลุดโดยไม่ได้วางแผนและความคงที่ของสัญญาณชีพของทารกเกิดก่อนกำหนด : การศึกษากึ่งทดลอง

อังศุมาลิน แสงงาม จุฑามาศ โชติบาง พัชรี วรกิจพูนผล*

บทคัดย่อ: ทารกเกิดก่อนกำหนดอายุครรภ์น้อยกว่า 34 สัปดาห์ มีปัญหาระบบทางเดินหายใจ ต้องได้รับการช่วยชีวิตด้วยการใส่ท่อและเครื่องช่วยหายใจ ท่อช่วยหายใจเลื่อนหลุดเป็นปัญหาที่พบบ่อยและส่งผลกระทบหลายด้าน วิจัยนี้มีวัตถุประสงค์เพื่อเปรียบเทียบอัตราการเกิดท่อช่วยหายใจเลื่อนหลุดโดยไม่ได้วางแผน ค่าความคงที่ของสัญญาณชีพและค่าความอิ่มตัวของออกซิเจนระหว่างกลุ่มควบคุม (n = 24) ที่ได้รับการดูแลและป้องกันท่อเลื่อนหลุดตามปกติของหอผู้ป่วยหนักทารกแรกเกิด กับกลุ่มทดลอง (n = 24) ที่ได้รับการดูแลและป้องกันท่อเลื่อนหลุดตามปกติร่วมกับใช้ชุดอุปกรณ์ปรับความคงที่และสัญญาณชีพที่อยู่ในเกณฑ์ปกติทารกเกิดก่อนกำหนด ได้แก่ อัตราการเต้นของหัวใจ การหายใจ และความอิ่มตัวของออกซิเจน เครื่องมือที่ใช้ คือ ชุดอุปกรณ์ปรับความคงที่ของท่อช่วยหายใจ ประกอบด้วยหมวกยึดตรึงท่อช่วยหายใจ หมอนพยุงคอที่ปรับขนาดได้ และเครื่องวัดออกซิเจน วิเคราะห์ข้อมูลโดยใช้สถิติบรรยาย การทดสอบค่าที การทดสอบไคสแควร์ และการทดสอบของฟิชเชอร์

ผลการวิจัยพบว่า กลุ่มควบคุมมีระยะเวลาใส่ท่อช่วยหายใจเฉลี่ย 78.94 ชั่วโมง และกลุ่มทดลองมีระยะเวลาใส่ท่อช่วยหายใจเฉลี่ย 39.35 อัตราการเลื่อนหลุดของท่อช่วยหายใจร้อยละ 33.33 (8 ราย) ในกลุ่มควบคุมและร้อยละ 4.17 (1 ราย) ในกลุ่มทดลอง อีกทั้งอัตราการเลื่อนหลุดของท่อช่วยหายใจต่อ 100 วันการใส่ท่อช่วยหายใจ ในกลุ่มทดลองเท่ากับ 4.41 ครั้ง ซึ่งน้อยกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ (23.84 ครั้ง) และกลุ่มทดลองพบร้อยละของจำนวนครั้งสัญญาณชีพที่อยู่ในเกณฑ์ปกติมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ดังนั้น การนำชุดปรับความคงที่ของท่อช่วยหายใจในทารกแรกเกิดเข้าสู่การปฏิบัติงานของพยาบาลอาจส่งผลให้การดูแลผู้ป่วยดีขึ้น ลดความซับซ้อน และมีผลลัพธ์ที่ดีกว่า ชุดอุปกรณ์ได้ผ่านการประเมินความเป็นไปได้ในการเป็นสิทธิบัตรเชิงลึกด้านการออกแบบผลิตภัณฑ์ อย่างไรก็ตาม ในการศึกษาครั้งต่อไปควรศึกษาในหน่วยที่แตกต่างกันโดยมีขนาดกลุ่มตัวอย่างที่มีขนาดใหญ่ขึ้นและระยะเวลาการใส่ท่อช่วยหายใจโดยเฉลี่ยที่เท่ากันระหว่างทั้งสองกลุ่ม เพื่อเป็นการยืนยันผลการศึกษา

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คำสำคัญ: ชุดอุปกรณ์ปรับความคงที่ ท่อช่วยหายใจ หอผู้ป่วยหนักทารกแรกเกิด ทารกเกิดก่อนกำหนด ท่อช่วยหายใจเลื่อนหลุดโดยไม่ได้วางแผน สัญญาณชีพ

อังศุมาลิน แสงงาม *นักศึกษาหลักสูตรพยาบาลศาสตรมหาบัณฑิต สาขาวิชาการพยาบาลเด็ก คณะพยาบาลศาสตร์ มหาวิทยาลัยเชียงใหม่*
E-mail: Aungsumalin_s@cmu.ac.th
ติดต่อที่ : จุฑามาศ โชติบาง *รองศาสตราจารย์ คณะพยาบาลศาสตร์ มหาวิทยาลัยเชียงใหม่ E-mail: jutamas.c@cmu.ac.th*
พัชรี วรกิจพูนผล *รองศาสตราจารย์ คณะพยาบาลศาสตร์ มหาวิทยาลัยเชียงใหม่*
E-mail: patcharee.w@cmu.ac.th