

# Prophylactic Helmet NIV versus Facemask NIV on Extubation Success in Nonsurgical Postextubation Patients with Preexisting Cardiac Disease

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**Background:** Noninvasive ventilation (NIV) prevents postextubation respiratory failure among high-risk patients. While clinical trials have shown no statistical significance in extubation success between facemask NIV and helmet NIV, subgroup analysis among high-risk patients with preexisting cardiac disease did not reveal conclusive evidence.

**Objective:** To assess the subgroup analysis of patients with preexisting cardiac disease in extubation success rate within the first 48 hours between helmet NIV and facemask NIV.

**Materials and Methods:** A retrospective cohort study from a randomized control trial examined patients at high-risk for extubation failure due to preexisting cardiac disease between June 2022 and June 2023. The primary outcome was extubation success within the first 48 hours. Secondary outcomes included reintubation rate within 7 days, NIV intolerance rate, complications, comfort score, and hemodynamic and gas exchange parameters during the study period.

**Results:** Among the 114 patients, 44 met the criteria for high-risk extubation failure due to preexisting cardiac disease (19 had facemask NIV, 25 used helmet NIV). Baseline characteristics showed no significant differences between the two groups, except for age ( $76.58 \pm 10.41$  versus  $67.08 \pm 16.75$ ,  $p=0.04$ ) and APACHE II score ( $16.58 \pm 1.77$  versus  $14.88 \pm 2.42$ ,  $p=0.02$ ). The extubation success rate was comparable between the two groups (helmet NIV, 84%; facemask NIV, 89.47%;  $p=0.68$ ). The pressure support setting was higher in helmet NIV than in facemask NIV ( $12.36 \pm 2.69$  versus  $8.32 \pm 2.10$ ;  $p<0.001$ ). Helmet NIV showed lower air leakage from baseline to 24 hours after extubation compared to facemask NIV ( $p<0.001$ ). NIV intolerance rate was significantly higher in the helmet group than in the control group (80% versus 21.05%,  $p<0.001$ ). No intergroup differences were observed in pH,  $\text{PaO}_2/\text{FiO}_2$ , and  $\text{PaCO}_2$ . The reintubation rate within 7 days was identical between the groups. The incidence of adverse events related to pressure sores was lower but higher concerning noise in the helmet group than in the facemask group ( $p<0.001$ ).

**Conclusion:** In the subgroup analysis focusing on preexisting cardiac disease in individuals at high-risk for postextubation respiratory failure, helmet NIV did not significantly differ in the extubation success rate compared with facemask NIV.

**Keywords:** Helmet NIV; Facemask NIV; High-risk extubation failure; Extubation success, Preexisting cardiac disease

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Postextubation respiratory failure, particularly within the first 48 hours after extubation, contributes to a high

mortality rate in ICU patients, requiring strategies to reduce this complication<sup>(1)</sup>. A strategy for preventing reintubation in patients at high-risk for extubation failure is noninvasive mechanical ventilation (NIV)<sup>(2)</sup>. Recent international guidelines recommend providing NIV after extubation in patients at risk for postextubation respiratory failure<sup>(3)</sup>. Several studies have revealed the efficacy of NIV over conventional oxygen therapy in decreasing the reintubation rate<sup>(4-6)</sup>. Concurrently, a recent meta-analysis and systematic review have shown that NIV reduce reintubation in high-risk patients<sup>(7)</sup>.

Patients who are at risk for postextubation respiratory failure should be promptly identified before using NIV immediately after extubation. The high-risk factors for postextubation respiratory failure include age >65 years,

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preexisting cardiac or lung disease, APACHE II score >12, BMI >30 kg/m<sup>2</sup>, difficult or prolonged weaning for more than 7 days, and a Charlson Comorbidity Index >2 on the day of extubation<sup>(4,8-10)</sup>. When used with positive end-expiratory pressure (PEEP), NIV optimizes gas exchange and reduces the work of breathing by stenting the upper airway and increasing alveolar recruitment<sup>(2)</sup>. Managing postextubation respiratory failure involves setting the optimal setup and selecting the appropriate interface. Facemask NIV is a practical interface; however, no studies comparing it to other interfaces have been conducted to determine the reduction in the reintubation rate. Patients using facemasks have shown limited efficacy due to air leakage and ineffective pressure demand, which can lead to respiratory failure requiring reintubation<sup>(11)</sup>.

The helmet interface was commonly used during the COVID-19 pandemic, which has demonstrated efficacy in preventing intubation in hypoxemic respiratory failure<sup>(12)</sup>. Meta-analyses have revealed that helmet NIV, comprising a transparent hood, a padded collar fastened around the neck, and straps fastened beneath the wearer's armpits, reduced in-hospital mortality and reintubation rates compared with facemask NIV<sup>(13-15)</sup>. However, studies on the efficacy of helmet NIV in preventing postextubation respiratory failure are limited<sup>(16)</sup>. A randomized controlled trial (RCT) conducted in patients at high-risk for extubation failure compared helmet and facemask NIV but found no statistically significant difference in extubation success<sup>(17)</sup>. Thus, this retrospective cohort study from an RCT aims to compare the 48-hour extubation success between different interfaces in subgroup analysis of high-risk factors due to preexisting cardiac disease.

## Materials and Methods

### Study design

A retrospective cohort study, derived from a randomized control trial (RCT) conducted between June 2022 and June 2023, including patients with increased risk of extubation failure in a university hospital was performed.

### Population and environment

The present study was conducted at King Chulalongkorn Memorial Hospital, Thai Red Cross Society, Bangkok, Thailand. Written informed consent was obtained from all patients or their closest relative before inclusion in the study. Subsequently, a retrospective analysis was performed following the initial results obtained from the randomized controlled trial titled "Comparison of Extubation Success between Prophylactic Helmet NIV and facemask NIV in High-Risk Postextubation Patients; A RCT", which received approval from the Institutional Review Board, Faculty of Medicine Vajira Hospital (IRB number 186/66

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This is a subgroup analysis involving patients at high-risk for extubation failure, particularly those with preexisting cardiac disease, based on specific criteria. These criteria include age >65 years, preexisting chronic cardiac or lung disease, APACHE II score >12, BMI >30 kg/m<sup>2</sup>, difficult or prolonged weaning for more than 7 days, and Charlson Comorbidity Index >2 on the day of extubation. Preexisting cardiac disease was defined as left ventricular dysfunction (ejection fraction, LVEF <45% from any cause), a history of cardiogenic pulmonary edema, documented ischemic heart disease, or permanent atrial fibrillation. Additionally, preexisting chronic pulmonary diseases included chronic obstructive pulmonary disease, obesity hypoventilation syndrome, and restrictive lung disease from any cause. The exclusion criteria were long-term NIV use, chronic neuromuscular disease, traumatic brain injury requiring intubation, accidental or self-extubation, do-not-resuscitate status after extubation, and contraindications to NIV.

Among 114 patients, 44 met the criteria for high-risk extubation failure due to preexisting cardiac disease, with 19 and 25 using facemask and helmet NIV, respectively.

### Methodology

During the study, either a helmet or facemask interface was utilized with critical care ventilator. The initial ventilator setting was well-protocolized, with PEEP set at 5 cmH<sub>2</sub>O, gradually increasing by 2 to 3 cmH<sub>2</sub>O from baseline to achieve oxygen saturation >90% with FiO<sub>2</sub> <0.6. Pressure support was applied for increased PEEP level of at least 4 cmH<sub>2</sub>O, gradually increasing by 2 to 3 cmH<sub>2</sub>O to maintain a respiratory rate below 30 breaths/min. Both interfaces were continued in each group for 24 hours after extubation. Besides the dissimilarity of the interface, both groups received identical standard treatment and nursing care and management in strict adherence to protocol. A 4-hour break, with a maximum of 60 minutes per session, was provided to both the intervention and control groups. During the break, an oxygen cannula with a flow rate of 1 to 5 liters/minute was administered to achieve oxygen saturation >90%. The total duration of NIV use was at least 18 hours. After NIV, an oxygen cannula delivering 1 to 5 liters/minute was used to maintain oxygen saturation >90%. NIV intolerance was defined as patient discomfort after adjusting to a well-protocolized ventilator setting without signs and symptoms of postextubation respiratory failure. In patients with NIV intolerance, a high-flow nasal cannula with a flow rate of 50 liters/minute and FiO<sub>2</sub> adjusted to achieve oxygen saturation of at least 92% was used<sup>(18)</sup>.

### Outcomes

The primary outcome of this study was the success

of extubation within 48 hours, with the absence of postextubation respiratory failure requiring reintubation. Postextubation respiratory failure was defined as meeting at least two of the following criteria: respiratory rate >35 breaths/minute for at least 2 hours and heart rate >140 beats/min or 20% increase or decrease from baseline; suspected respiratory muscle failure due to increased work of breathing; respiratory acidosis defined as pH <7.30 and pCO<sub>2</sub> >45 mmHg or 20% increase from baseline; and FiO<sub>2</sub> >0.5 required to maintain oxygen saturation above 90% or PaO<sub>2</sub> >60 mmHg. Furthermore, in delineating criteria for prompt reintubation after postextubation respiratory failure, we identified the following: hemodynamic failure, defined as systolic blood pressure <90 mmHg or mean arterial pressure <65 mmHg requiring vasopressor therapy; neurological failure, defined as a Glasgow Coma Score <13 or unusually high levels of restlessness; and cardiac or respiratory arrest<sup>(19)</sup>.

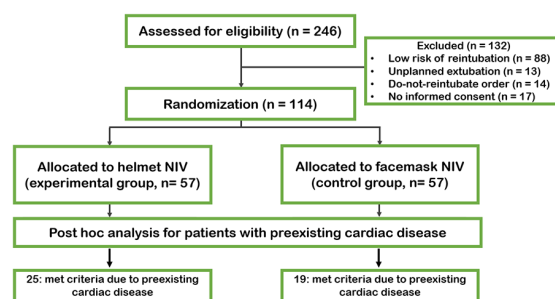
The secondary outcomes included reintubation rate within 7 days, reintubation etiologies, reintubation time, NIV intolerance rate, complications from NIV use, NIV comfort score, respiratory and gas exchange parameters (i.e., respiratory rate, PaO<sub>2</sub>/FiO<sub>2</sub>, SaO<sub>2</sub>/FiO<sub>2</sub>, PCO<sub>2</sub>, pH, and work of breathing score), and hemodynamic parameters (i.e., heart rate and mean arterial pressure) at 30 minutes and 2, 24, and 48 hours following extubation.

## Statistical analysis

Data of all enrolled patients meeting the inclusion criteria were analyzed by a blinded statistician. Categorical variables, expressed as numbers and percentages, were compared using Fisher's exact test. Continuous variables, presented as mean or median, were compared using either an independent t-test or the Wilcoxon signed-rank test, depending on the data distribution. Intention-to-treat and per-protocol analyses were conducted. The p-value <0.05 was deemed statistically significant. Stata 16 was utilized for all analyses.

## Results

In the study, 114 patients met the inclusion criteria and were randomly assigned to receive either facemask NIV or helmet NIV, with 44 patients identified as high-risk due to preexisting cardiac disease (19 had facemask NIV, and 25 underwent helmet NIV) (Figure 1). Table 1 presents the baseline characteristics of both patient groups. Similarities were observed in BMI, underlying diseases, baseline comorbidities, severity scores of current diseases (including SOFA scores and Charlson Comorbidity Index), and baseline hemodynamics and gas exchange parameters. Furthermore, the etiologies of respiratory failure and duration of mechanical ventilation were comparable between the



**Figure 1.** Flow chart of participants in the study.

groups. However, the facemask NIV group exhibited higher age, APACHE II score, and positive net fluid balance than the helmet NIV group ( $p=0.04$ ,  $0.02$ , and  $0.032$ , respectively). The pressure support (PS) and inspired (VTi) and expired (VTe) tidal volumes were greater in helmet NIV than in facemask NIV (PS:  $12.36\pm2.69$  versus  $8.32\pm2.10$ ,  $p<0.001$ ; VTi:  $1,184.68\pm171.97$  versus  $528.95\pm100.52$ ,  $p<0.001$ ; and VTe:  $1,062.20\pm163.31$  versus  $418.89\pm82.94$ ,  $p<0.001$ ). Significantly less air leakage was observed in the helmet NIV group compared with the facemask NIV group ( $10.40\pm2.24$  versus  $21.88\pm10.12$ ,  $p<0.001$ ). However, NIV intolerance was significantly higher in the helmet NIV group, resulting in a lower median duration of helmet NIV compared to facemask NIV ( $9.02\pm8.59$  versus  $20.84\pm7.13$ ,  $p<0.001$ ). FiO<sub>2</sub> and PEEP settings were comparable between the groups.

## Primary outcome

Among patients with high-risk factors due to preexisting cardiac disease, the extubation success within the first 48 hours showed no significant difference between helmet and facemask NIV, with success rates of 89.47% versus 84% ( $p=0.684$ ) (Table 2).

## Secondary outcomes

The rate of reintubation within 7 days and reintubation time were similar between helmet and facemask NIV. Moreover, the reasons for reintubation were identical in both groups. Facemask NIV resulted in a higher pressure sore score ( $1.53\pm0.90$  versus  $0.44\pm0.65$ ,  $p<0.001$ ). The noise level was greater in the helmet NIV group (64% versus 0%,  $p<0.001$ ). More leakage was detected in helmet NIV than in facemask NIV. Additionally, the helmet NIV group exhibited a lower mean arterial pressure throughout the 48-hour postextubation period. Other secondary outcomes were comparable between helmet and facemask NIV (Tables 3 and 4).

## Discussion

In a retrospective cohort study, the use of helmet NIV

**Table 1.** Patients' baseline characteristics

Characteristics	Facemask NIV (n=19)	Helmet NIV (n=25)	p-value
Gender Male, n (%)	12 (63.10)	18 (72.00)	0.53
Age (years), mean $\pm$ SD	76.58 $\pm$ 10.41	67.08 $\pm$ 16.75	0.04
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	26.13 $\pm$ 5.37	24.63 $\pm$ 5.32	0.36
Underlying diseases, n (%)			
Hypertension	17 (89.40)	22 (88.00)	> 0.05
Diabetes mellitus	15 (78.90)	17 (68.00)	0.42
Congestive heart failure	14 (73.70)	19 (76.00)	> 0.05
Renal impairment	17 (89.40)	20 (80.00)	0.45
Conservative treatment	8 (42.10)	9 (36.00)	0.68
Renal replacement therapy	9 (47.30)	12 (48.00)	0.97
Cirrhosis	3 (15.80)	2 (8.00)	0.64
Airway diseases	3 (15.80)	5 (20.00)	> 0.05
COPD	2 (10.50)	2 (8.00)	> 0.05
Asthma	0 (0.00)	1 (4.0)	> 0.05
Bronchiectasis	1 (5.30)	1 (4.00)	> 0.05
Tracheobronchomalacia	0 (0.00)	1 (4.00)	> 0.05
Cancer	1 (5.3)	3 (12.0)	0.62
Former	0 (0.00)	1 (4.00)	> 0.05
Current	1 (5.30)	2 (8.00)	> 0.05
Type of malignancy			
Head & Neck Cancer	-	-	
Lung cancer	1 (5.30)	0 (0.00)	0.43
Gastrointestinal malignancy	-	-	
Gynecologic malignancy	-	1 (4.00)	> 0.05
Breast cancer	-	-	
Hematologic malignancy	0 (0.00)	2 (8.00)	0.50
The severity of the current disease and pre-existing comorbidities			
Charlson Comorbidity Index, mean $\pm$ SD	7.63 $\pm$ 1.89	6.00 $\pm$ 2.77	0.05
APACHE II, mean $\pm$ SD	16.58 $\pm$ 1.77	14.88 $\pm$ 2.42	0.02
SOFA score, mean $\pm$ SD	3.89 $\pm$ 1.76	3.96 $\pm$ 1.95	0.98
Vital signs			
RR (rpm), mean $\pm$ SD	18.47 $\pm$ 3.50	19.48 $\pm$ 3.03	0.43
MAP (mmHg), mean $\pm$ SD	87.21 $\pm$ 13.35	85.40 $\pm$ 10.80	0.95
HR (bpm), mean $\pm$ SD	86.95 $\pm$ 13.04	87.72 $\pm$ 13.90	0.84
Gas exchange			
PaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	328.06 $\pm$ 73.86	361.51 $\pm$ 73.97	0.26
SaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	330.68 $\pm$ 72.73	350.02 $\pm$ 61.24	0.36
pCO <sub>2</sub> (mmHg), mean $\pm$ SD	29.45 $\pm$ 4.84	31.2 $\pm$ 5.77	0.73
pH, mean $\pm$ SD	7.46 $\pm$ 0.05	7.46 $\pm$ 0.04	0.65
Weaning parameters			
Work of breathing score, mean $\pm$ SD	1.52 $\pm$ 0.697	1.53 $\pm$ 0.586	0.87
RSBI, mean $\pm$ SD	77.87 $\pm$ 13.68	82.84 $\pm$ 13.79	0.24
CPF (LPM), mean $\pm$ SD	190.52 $\pm$ 63.20	190.80 $\pm$ 32.80	0.58
NIF (cmH <sub>2</sub> O), mean $\pm$ SD	-24.15 $\pm$ 4.75	-23.8 $\pm$ 4.35	0.80
Weaning time (minutes), mean $\pm$ SD	44.84 $\pm$ 11.22	50.04 $\pm$ 13.76	0.15

SD=standard deviation; N=number of patients; No.=number; COPD=chronic obstructive pulmonary disease; CNS=central nervous system; RR=respiratory rate, MAP=mean arterial pressure; HR=heart rate; RSBI=rapid shallow breathing index; CPF=cough peak flow; NIF=negative inspiratory force; ARDS=acute respiratory distress syndrome; DAH=diffuse alveolar hemorrhage; PEEP=positive end expiratory pressure; PS=pressure support; VTi=inspired tidal volume; VTe=expired tidal volume; FiO<sub>2</sub>=fraction of inspired oxygen; NIV=non-invasive ventilation

Table 1. Cont.

Characteristics	Facemask NIV (n=19)	Helmet NIV (n=25)	p-value
Causes of respiratory failure, n (%)			
Pulmonary causes	13 (68.40)	21 (84.00)	0.29
Pneumonia	6 (31.60)	6 (24.00)	0.58
ARDS	1 (5.30)	1 (4.00)	> 0.05
Bronchospasm	2 (10.60)	3 (12.00)	> 0.05
Pulmonary edema	9 (47.40)	15 (60.00)	0.41
Extra-pulmonary causes	10 (52.60)	11 (44.00)	0.57
Sepsis	8 (42.10)	9 (36.00)	0.68
Metabolic acidosis from other causes	5 (26.30)	7 (28.00)	0.90
Comatose status	1 (5.30)	0 (0.00)	0.43
Hemorrhagic shock	3 (15.80)	1 (4.00)	0.30
Duration of mechanical ventilation before extubation (days), mean ± SD	5.79±4.69	4.52±2.24	0.24
NIV settings			
PEEP (cmH <sub>2</sub> O), mean ± SD	5.68±1.15	6.40±1.38	0.06
PS (cmH <sub>2</sub> O), mean ± SD	8.32±2.10	12.36±2.69	<0.001*
VTi (mL), mean ± SD	528.95±100.52	1184.68±171.97	<0.001*
VTe (mL), mean ± SD	413.89±82.94	1062.20±163.31	<0.001*
FiO <sub>2</sub> , mean ± SD	0.30±0.06	0.30±0.05	0.84
% Leakage at baseline, mean ± SD	21.88±10.12	10.40±2.24	<0.001*
NIV duration (hours), mean ± SD	20.84±7.13	9.02±8.59	<0.001*

SD=standard deviation; N=number of patients; No.=number; COPD=chronic obstructive pulmonary disease; CNS=central nervous system; RR=respiratory rate, MAP=mean arterial pressure; HR=heart rate; RSBI=rapid shallow breathing index; CPF=cough peak flow; NIF=negative inspiratory force; ARDS=acute respiratory distress syndrome; DAH=diffuse alveolar hemorrhage; PEEP=positive end expiratory pressure; PS=pressure support; VTi=inspired tidal volume; VTe=expired tidal volume; FiO<sub>2</sub>=fraction of inspired oxygen; NIV=non-invasive ventilation

Table 2. Primary outcome: successful extubation in the first 48 hours

Primary outcome	Facemask NIV	Helmet NIV	p-value
Successful, n (%)	17 (89.47)	21 (84.00)	0.68
Failure, n (%)	2 (10.53)	4 (16.00)	

immediately after extubation in patients with a high-risk of extubation failure due to preexisting cardiac disease showed no difference in 48-hour extubation success compared to facemask NIV.

A recent meta-analysis reported that helmet NIV has been indicated for preventing intubation in acute hypoxemic respiratory failure. However, its efficacy in preventing reintubation in patients at risk for postextubation respiratory failure has not been strongly established as the evidence supporting facemask NIV use<sup>(12,14)</sup>. We hypothesize that helmet NIV may outperform facemask NIV in preventing reintubation in patients with cardiac disease owing to its greater stability of airway pressure and ability to allow higher levels of PEEP and pressure support<sup>(20,21)</sup>. This could improve cardiac performance, particularly in patients with left ventricular dysfunction. Additionally, higher PEEP levels may minimize the risk of lung injury, a condition that facemask NIV cannot address because of patient discomfort and air leakage. The

use of helmet NIV in cardiogenic pulmonary edema has shown favorable outcomes in improving hemodynamic parameters compared to facemask NIV<sup>(22)</sup>. This indicates a strong recommendation for the use of helmet NIV in cardiogenic pulmonary edema. To our knowledge, only one RCT compared helmet NIV with facemask NIV in high-risk postextubation patients and demonstrated no significant difference in 48-hour extubation success rates<sup>(17)</sup>. This study aimed to further investigate extubation success in a subgroup analysis of high-risk patients with preexisting cardiac disease from the previous RCT<sup>(17)</sup> to determine whether there is a difference in extubation success. Despite helmet NIV showing lower percentages of air leakage and higher levels of pressure support, our study revealed no difference in extubation success rates between helmet and facemask NIV. Additionally, subgroup analysis revealed higher NIV intolerance rate, which was similar to previous RCT findings but contrasted with those of other studies<sup>(17,21,23,24)</sup>. After adjusting PS and PEEP according to well-protocolized standards, the median duration of helmet NIV use was 9 hours. Patients requested helmet removal because of discomfort, despite lacking signs and symptoms of postextubation respiratory failure. Concerning findings regarding higher helmet NIV intolerance rate were noted, particularly in the Thai population. These results

**Table 3.** Secondary outcomes

Secondary outcomes	Facemask NIV (n=19)	Helmet NIV (n=25)	p-value
Reintubation rate within 7 days, n (%)	3 (15.79)	4 (16.00)	>0.05
Time to reintubation (days), mean $\pm$ SD	0.51 $\pm$ 1.55	0.30 $\pm$ 0.92	0.29
NIV intolerance, n (%)	4 (21.05)	20 (80.00)	<0.001*
Comfort score <sup>#</sup> , mean $\pm$ SD	4.95 $\pm$ 1.81	6.12 $\pm$ 1.94	0.048*
Adverse events			
Pressure sore score, mean $\pm$ SD	1.53 $\pm$ 0.90	0.44 $\pm$ 0.65	<0.001*
Secretion obstruction, n (%)	1 (5.30)	0 (0.00)	0.43
Nasal irritation, n (%)	2 (10.60)	0 (0.00)	0.18
Hot air, n (%)	5 (26.31)	5 (20.00)	0.72
Noise, n (%)	0 (0.00)	16 (64.00)	<0.001*
Asynchrony, n (%)	4 (21.05)	1 (4.00)	0.15
Others, n (%)	0 (0.00)	2 (8.00)	0.50
30 minutes after extubation			
RR (rpm), mean $\pm$ SD	20.37 $\pm$ 2.67	20.44 $\pm$ 2.20	0.92
MAP (mmHg), mean $\pm$ SD	90.53 $\pm$ 13.42	85.36 $\pm$ 10.88	0.17
HR (bpm), mean $\pm$ SD	88.63 $\pm$ 9.62	87.24 $\pm$ 13.24	0.70
SaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	340.74 $\pm$ 68.12	350.74 $\pm$ 58.67	0.46
% Leakage, median [Q1, Q3]	19.74 $\pm$ 6.85	10.72 $\pm$ 2.37	< 0.001*
WOB score, median [Q1, Q3]	1.58 $\pm$ 0.61	1.56 $\pm$ 0.51	0.98
2 hours after extubation			
RR (rpm), mean $\pm$ SD	20.21 $\pm$ 2.72	20.48 $\pm$ 2.28	0.86
MAP (mmHg), mean $\pm$ SD	91.79 $\pm$ 11.62	86.72 $\pm$ 10.67	0.27
HR (bpm), mean $\pm$ SD	91.53 $\pm$ 12.55	86.88 $\pm$ 13.14	0.24
SaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	345.34 $\pm$ 62.89	355.54 $\pm$ 61.63	0.75
PaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	402.52 $\pm$ 132.18	408.60 $\pm$ 82.40	0.85
pCO <sub>2</sub> (cmH <sub>2</sub> O), mean $\pm$ SD	30.77 $\pm$ 4.30	31.80 $\pm$ 5.19	0.49
pH, mean $\pm$ SD	7.45 $\pm$ 0.05	7.45 $\pm$ 0.04	0.52
% Leakage, median [Q1, Q3]	22.68 $\pm$ 10.51	9.48 $\pm$ 2.80	< 0.001*
WOB score, median [Q1, Q3]	1.53 $\pm$ 0.61	1.40 $\pm$ 0.50	0.54
24 hours after extubation			
RR (rpm), mean $\pm$ SD	19.26 $\pm$ 2.70	19.56 $\pm$ 2.16	0.93
MAP (mmHg), mean $\pm$ SD	87.53 $\pm$ 11.61	85.36 $\pm$ 9.94	0.45
HR (bpm), mean $\pm$ SD	86.53 $\pm$ 10.79	85.08 $\pm$ 10.23	0.79
SaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	344.77 $\pm$ 64.80	360.70 $\pm$ 65.53	0.43
PaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	409.93 $\pm$ 93.70	397.07 $\pm$ 83.12	0.64
pCO <sub>2</sub> (cmH <sub>2</sub> O), mean $\pm$ SD	30.37 $\pm$ 4.76	31.70 $\pm$ 4.72	0.36
pH, mean $\pm$ SD	7.44 $\pm$ 0.03	7.46 $\pm$ 0.03	0.24
% Leakage, median [Q1, Q3]	20.94 $\pm$ 11.81	8.50 $\pm$ 1.73	0.02*
WOB score, median [Q1, Q3]	1.37 $\pm$ 0.50	1.28 $\pm$ 0.46	0.54
48 hours after extubation			
RR (rpm), mean $\pm$ SD	19.42 $\pm$ 2.24	19.16 $\pm$ 1.57	0.65
MAP (mmHg), mean $\pm$ SD	87.95 $\pm$ 11.72	84.36 $\pm$ 9.05	0.27
HR (bpm), mean $\pm$ SD	86.11 $\pm$ 11.70	84.84 $\pm$ 10.91	0.75
SaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	348.20 $\pm$ 57.55	364.74 $\pm$ 60.43	0.36
PaO <sub>2</sub> /FiO <sub>2</sub> , mean $\pm$ SD	368.87 $\pm$ 60.10	360.16 $\pm$ 60.53	0.67
pCO <sub>2</sub> (cmH <sub>2</sub> O), mean $\pm$ SD	31.52 $\pm$ 4.67	31.86 $\pm$ 4.70	0.73
pH, mean $\pm$ SD	7.45 $\pm$ 0.04	7.45 $\pm$ 0.03	0.69
WOB score, median [Q1, Q3]	1.26 $\pm$ 0.45	1.20 $\pm$ 0.40	0.63

SD=standard deviation; N=number of patients, No.=number, RR=respiratory rate; MAP=mean arterial pressure; HR=heart rate; WOB score=work of breathing score; <sup>#</sup> the higher score, the more discomfort



**Table 4.** Etiologies of reintubation within seven days

Reasons for reintubation within seven days	Facemask NIV (n=19)	Helmet NIV (n=25)	p-value
Pulmonary cause	1 (5.30)	3 (12.00)	0.62
Pneumonia	0 (0.00)	1 (4.00)	>0.05
Secretion obstruction	0 (0.00)	2 (8.00)	0.50
Pulmonary edema	1 (5.30)	2 (8.00)	>0.05
Extrapulmonary cause	2 (10.60)	1 (4.00)	0.57
Sepsis	1 (5.30)	1 (4.00)	>0.05
Metabolic acidosis from other causes	1 (5.30)	0 (0.00)	0.43
Comatose status	1 (5.30)	0 (0.00)	0.43
Hemorrhagic shock	1 (5.30)	0 (0.00)	0.43

ARDS=acute respiratory distress syndrome; DAH=diffuse alveolar hemorrhage

are noteworthy as they contradict findings from other studies. Although used in the postextubation period, these findings indicate the use of helmet NIV over facemask NIV, especially for prolonged noninvasive mechanical ventilation<sup>(25)</sup>. In the previous RCT, no difference was found in hemodynamic parameters when comparing baseline measurements before randomization and those during intolerance episodes<sup>(17)</sup>. This shows that the discomfort experienced by patients was attributed to the device used. After a period of NIV intolerance, using a high-flow nasal cannula with a flow rate of 50 liters/minute and an adjusted FiO<sub>2</sub> should be considered to achieve oxygen saturation of at least 92%. This substitution may be a confounding factor in determining the primary outcome. During the study period, no differences were observed in hemodynamic and gas exchange parameters. This reveals that the helmet interface was as effective as other masks, whether used postextubation or in respiratory failure, in preventing the need for intubation.

Our results demonstrate consistency with other studies, indicating that helmet NIV can effectively mitigate complications linked with facemask NIV, such as pressure ulcers and eye or nasal irritation<sup>(21,25)</sup>. However, patients using helmet NIV encountered louder noise despite employing adequate earplugs than those using facemask NIV, possibly due to exposure of the entire head to positive pressure.

To our knowledge, the present study is the first to investigate the success of extubation in patients with preexisting cardiac conditions using helmet NIV during the postextubation period. Despite the limitations of being a retrospective cohort study conducted at a single center and the potential for being underpowered due to subgroup analysis, the present study may provide relevant insights to other healthcare systems. Moreover, the increased rate of NIV intolerance observed, consistent with findings from previous RCTs, may potentially influence the success rate of extubation<sup>(17)</sup>. Additionally, the learning curve and

education of the medical team in the use of helmet NIV in the Thai population setting may also play a significant role to improve the outcome<sup>(26)</sup>.

**Conclusion**

Compared with facemask NIV, helmet NIV did not significantly differ in extubation success rate in patients with high-risk of extubation failure due to preexisting cardiac disease.

**What is already known on this topic?**

Helmet NIV plays a significant role in preventing intubation in patients with acute respiratory failure<sup>(13-15)</sup>. However, evidence on postextubation use of helmet NIV particularly in patients with preexisting cardiac disease are few.

**What this study adds?**

Helmet NIV use during postextubation period in patients at risk for postextubation respiratory failure from preexisting cardiac disease showed no significant difference compared with facemask NIV.

**Conflicts of interest**

The authors declare no conflict of interest.

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